# Exhibit 129

### **REVIEW ARTICLE**

Dan L. Longo, M.D., Editor

### Mucinous Ovarian Carcinoma

Philippe Morice, M.D., Ph.D., Sebastien Gouy, M.D., Ph.D., and Alexandra Leary, M.D., Ph.D.

From the Departments of Gynecological Surgery and Medical Oncology (P.M., S.G., A.L.), INSERM Unit 981 (A.L.), and INSERM Unit 10-30 (P.M.), Gustave Roussy Cancer Campus, Villejuif, and University Paris-Sud (Paris XI), Le Kremlin Bicêtre (P.M.) — both in France. Address reprint requests to Dr. Morice at the Department of Gynecological Surgery, Gustave Roussy Cancer Campus, 94805 Villejuif CEDEX, France, or at philippe.morice@gustaveroussy.fr.

N Engl J Med 2019;380:1256-66. DOI: 10.1056/NEJMra1813254 Copyright © 2019 Massachusetts Medical Society. TEARLY 239,000 NEW CASES OF OVARIAN CANCER (AND 152,000 ASSOCIated deaths) are reported worldwide annually, with the highest incidence rates in North America and central and eastern Europe. The most common histologic subtype is high-grade serous ovarian cancer (accounting for 65% of cases). Other histologic subtypes include low-grade serous, endometrioid, clearcell, and mucinous ovarian cancers, as well as ovarian carcinosarcoma. Mucinous ovarian cancer is a rare tumor, probably accounting for 3% of all epithelial ovarian cancers, and often presents a diagnostic and therapeutic conundrum for oncologists. For decades, the management of mucinous ovarian cancer was based on guidelines developed for serous ovarian cancer. However, experience with mucinous ovarian cancer and an understanding of its biologic features have shown that it is a unique disease requiring unique management. This review highlights the distinguishing features of mucinous ovarian cancer and provides an update on its molecular landscape and surgical and medical management.

### A SEPARATE DISEASE ENTITY

The gene-expression profile of mucinous ovarian cancer is distinct from that of serous ovarian cancer.7 Sixty-five to 80% of mucinous ovarian cancers are diagnosed at an early stage, according to the classification of the International Federation of Gynecology and Obstetrics (FIGO stage I, defined as a tumor confined to a single ovary) (Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org).8 Patients with serous ovarian cancer tend to present at an advanced stage, with intraperitoneal spread in more than 80% of cases (Table 1).9,10 A potential explanation for this difference is that mucinous ovarian cancers are usually very large primary tumors (typically >15 cm in diameter) that generate symptoms while the disease is still localized to the ovary. Thus, the overall prognosis is much better for women with mucinous ovarian cancer than for those with other subtypes of epithelial ovarian cancer.8 Five-year overall survival among patients with localized mucinous ovarian cancer exceeds 90%; by contrast, when mucinous ovarian cancer has spread to the peritoneum in the abdominal cavity or beyond (stage III or IV), the estimated median overall survival is between 12 and 33 months. 9,11-16

Mucinous tumors are characteristically diagnosed in patients who are younger than patients in whom other epithelial ovarian cancers are diagnosed.<sup>6,9</sup> In a recent analysis of data from the Surveillance, Epidemiology, and End Results (SEER) cancer registry, 26% of mucinous ovarian cancers were diagnosed in women younger than 44 years.<sup>9</sup> Mucinous ovarian cancer is the most common histologic subtype in the subgroup of patients who are eligible for fertility-sparing surgery.<sup>17,18</sup>

Table 1. Epidemiologic, Clinical, and Pathological Features of Mucinous Ovarian Carcinoma as Compared with High-Grade Serous Ovarian Cancer.\* Mucinous Ovarian Carcinoma High-Grade Serous Ovarian Carcinoma Variable (prevalence, 3%) (prevalence, 65%) Age Median age at diagnosis (yr) 53 61 <44 yr at presentation (%) 26 5 Early stage at diagnosis (%) 65-80 Tumor marker CEA or CA 19-9 CA-125 Risk factors Smoking Nulliparity, early menarche, late menopause, germline BRCA1 or BRCA2 mutations Rate of response to platinum-based 20-60 chemotherapy (%) Overall survival Stage 1, at 5 yr (%) 92 84 Advanced stage, median (mo) 12-33 35-60

In a series of 545 patients undergoing such surgery, 51% (280 patients) had mucinous ovarian cancer.<sup>17</sup>

Most serous ovarian cancers originate in the fimbria of the fallopian tubes.19 Mucinous ovarian cancers appear to evolve in stepwise fashion from benign epithelium to a preinvasive lesion to carcinoma (Fig. 1).3,5,20,21 Mucinous ovarian cancer is frequently mixed with areas of mucinous cystadenoma or precancerous lesions (borderline mucinous tumor, borderline tumor with intraepithelial carcinoma, microinvasive carcinoma, or a combination of such lesions). This continuum of malignant progression is in stark contrast to the development of serous ovarian cancer and is similar to the development of colorectal cancer. KRAS mutations are observed in 40 to 65% of mucinous carcinomas. The same KRAS mutation has been detected in the carcinoma foci and in surrounding borderline malignant and benign areas, suggesting that the mutation is an early founder event. 22-24 Other genomic alterations such as HER2 amplification or TP53 mutation are almost exclusively observed in the carcinomatous component of mucinous tumors, supporting the view that these alterations represent later events in malignant transformation. 23,24 Another hypothesis regarding the histogenesis of mucinous ovarian cancers is that they may be derived from transitional cells (Walthard cell nests are observed in 59% of mucinous neoplasms) or metaplasia at the fallopian tube-peritoneal junction.<sup>25</sup>

Risk factors for serous ovarian cancer include nulliparity, early menarche, late menopause, and germline BRCA1 or BRCA2 mutations, none of which are risk factors for mucinous ovarian cancer. The only clinical risk factor associated with mucinous ovarian cancer is tobacco smoking. A genomewide association study of 1644 mucinous ovarian cancers identified susceptibility alleles at 2q13, 2q31.1, and 19q13.2 (the potential candidate gene is HOXD9 for locus 2q31.1).<sup>26</sup> The incidence of mucinous ovarian cancer decreased by 5% annually in the United States between 1995 and 2009 and has been stable since 2009.10 These trends could be attributable to a decline in smoking or to improvements in the histologic diagnosis of mucinous ovarian cancer in the late 1990s and early 2000s. 10,27,28

### DIAGNOSTIC CHALLENGE

Early reports probably overestimated the prevalence of mucinous ovarian cancer, with some studies reporting that they represented 10 to 15% of epithelial ovarian cancers. 9,29,30 However, a central pathological review of ovarian tumors

<sup>\*</sup> Some of the data presented in the table are from Ferlay et al.,1 Reid et al.,2 Peres et al.,9 and Torre et al.10 CEA denotes carcinoembryonic antigen.

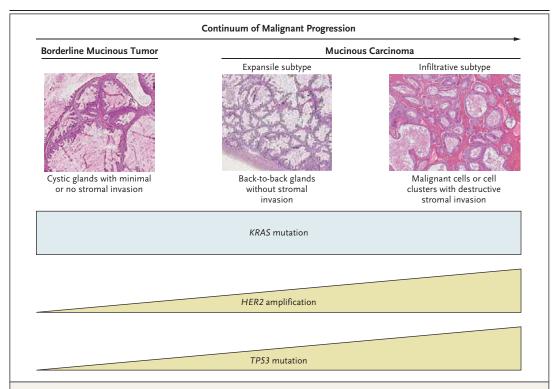


Figure 1. Stages in the Progression of Mucinous Ovarian Tumors.

Mucinous ovarian tumors develop on a continuum from benign epithelium to preinvasive (borderline) carcinoma to mucinous carcinoma. KRAS mutations are an early event, whereas other oncogenic alterations (HER2 amplifications or TP53 mutations) may be acquired later in the course of malignant transformation.

initially classified as primary ovarian mucinous carcinomas revealed that 50 to 70% were in fact metastases from other sites. According to different reports, the true proportion of ovarian epithelial cancers that are mucinous ovarian cancers is closer to 1 to 3%.<sup>29,31</sup>

## RULING OUT OVARIAN METASTASES FROM NONOVARIAN OCCULT PRIMARY CANCER

A combination of clinical, pathological, and immunohistochemical investigations is useful in distinguishing a primary mucinous ovarian tumor from metastatic disease to the ovary (Krukenberg tumor) (Fig. 2).<sup>29,32,33</sup> A comprehensive work-up is performed to rule out an occult gastro-intestinal primary cancer (on the basis of colonoscopy and upper gastrointestinal endoscopy, including endoscopic ultrasonography) or a cervical, breast, or uterine cancer.<sup>29,32</sup> These investigations are recommended if clinical or radiologic findings suggest a nonovarian primary cancer on the basis of tumor size (<10 cm

in diameter), the presence of bilateral tumors, peritoneal spread or another indication of advanced stage, or a combination of these findings (Fig. 2).<sup>29</sup>

### DIAGNOSING THE SUBTYPE OF MUCINOUS TUMOR

The diagnosis of mucinous ovarian carcinoma requires evidence of malignant proliferation covering an area of more than 10 mm<sup>2</sup> as determined on cross section. For decades, mucinous ovarian cancer was further classified as grade 1, 2, or 3 according to the presence or absence of nuclear atypia and the proportion of solid glandular component. However, in 2014, the World Health Organization (WHO) introduced a new diagnostic classification of mucinous ovarian carcinoma, with two categories according to the growth pattern: the expansile (confluent) subtype and the infiltrative subtype.5 The expansile subtype is characterized by a confluent glandular growth pattern, with little intervening normal ovarian stroma (minimal or no stromal in-

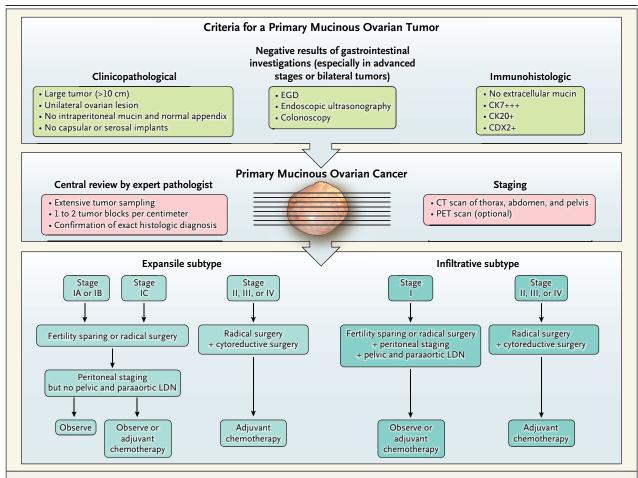


Figure 2. Overall Management of Mucinous Ovarian Tumors.

The first step in managing a primary mucinous ovarian tumor is to rule out mucinous metastasis to the ovary (a nonovarian primary mucinous cancer) on the basis of a combination of clinical and pathological features. Extensive sampling of these large heterogeneous tumors and review by an expert pathologist are required for accurate diagnosis. Once the diagnosis has been established, both staging and accurate histologic classification guide surgical and medical management. The plus signs in CK7+++, CK20+, and CDX2+ denote the intensity of positive staining on immunohistochemical analysis, with more plus signs indicating higher staining intensity. CT denotes computed tomography, EGD esophagogastroduodenoscopy, LDN lymphadenectomy, and PET positron-emission tomography.

vasion), whereas the infiltrative subtype is characterized by obvious evidence of destructive stromal invasion by malignant glands, cell nests, or individual cells and is often associated with a desmoplastic stromal reaction (Fig. 1).<sup>5,34</sup> several, albeit small, studies have confirmed that the risk of relapse for women with stage I expansile mucinous ovarian cancer is extremely low (3 recurrences were observed among 75 cases; 2 of the 3 were salvaged with secondary sur-

# PROGNOSTIC IMPLICATIONS OF THE WHO 2014 HISTOLOGIC CLASSIFICATION

The distinction between expansile and infiltrative subtypes is clinically important in stage I disease (Table 2), so surgical staging of these tumors is crucial.<sup>3-38</sup> The expansile growth pattern suggests a lower metastatic potential, and

that the risk of relapse for women with stage I expansile mucinous ovarian cancer is extremely low (3 recurrences were observed among 75 cases; 2 of the 3 were salvaged with secondary surgery). Moreover, more than 95% of women with expansile mucinous ovarian cancers present with stage I disease. Lase of the expansile subtype with peritoneal spread are very scarce (only 3 reported cases) (Table 2). Table 2). In contrast, infiltrative mucinous ovarian cancer is more aggressive, with at least 26% of women presenting with more advanced, nonlocalized

Table 2. Clinical Characteristics and Outcomes of Mucinous Ovarian Cancer According to the Subtype.	cs and Outcome	s of Mucinous Ovarian	Cancer According to t	he Subtype.		
Subtype and Study	Pathological Review	Total Enrollment	Stage IA	Stage IC	Higher Stage	Recurrences and Deaths
			יחע	number of patients		
Expansile subtype						
Riopel et al., 35 1999	Yes	5		**	l at stage II	l recurrence at stage II
Lee and Scully, <sup>34</sup> 2000	Yes	12 (10 in follow-up)	12	0	0	0 recurrences
Rodriguez and Prat, <sup>36</sup> 2002	Yes	15 (11 in follow-up)	10	5 (4 at stage IC1, 1 at stage IC2)	0	0 recurrences; 1 death from breast cancer
Muyldermans et al.,37 2013	Yes	23	11	10	2 at stage III	2 recurrences at stage III†
Gouy et al., <sup>38</sup> 2018	Yes	29	13	16 (9 at stage IC1, 5 at stage IC2, 2 at stage IC3)	Not included	3 recurrences: 1 at stage IA, 1 at stage IC2, 1 at stage IC3; 1 death
Total		84	46	31	8	6 recurrences: 3 at stage I (3/81 [4%]), 3 at higher stage (3/3 [100%])
Infiltrative subtype						
Hoerl and Hart, 39 1998		19		15‡	4 at stage III	6 recurrences: 2 at stage 1, 4 at higher stages; 5 deaths
Lee and Scully,³⁴ 2000		13 (11 in follow-up)	6 (5 in follow-up)	0	3 at stage II, 3 at stage III, 1 at stage IV (5 in follow-up)	6 recurrences: 1 at stage IA, 5 at higher stages; 6 deaths
Rodriguez and Prat, <sup>36</sup> 2002		19 (15 in follow-up)	∞	ю	1 at stage II, 6 at stage III, 1 at stage IV (6 in follow-up)	9 recurrences: 1 at stage IC1, 2 at stage IC2, 1 at stage II, 4 at stage III, 1 at stage IV; 7 deaths
Muyldermans et al., <sup>37</sup> 2013		21	6	3	9 at stage III	9 recurrences: 1 at stage IA, 1 at stage IC, 7 at stage III
Gouy et al.,38 2018		35	20	15 (7 at stage IC1, 7 at stage IC2, 1 at stage IC3)	Not included	6 recurrences: 2 at stage IA, 1 at stage IC1, 2 at stage IC2, 1 at stage IC3; 4 deaths¶
Total		107	43	21	28	36 recurrences: 14 at stage   (14/79 [18%]) and 22 at stage III or IV (22/24 [92%])

In this study, four patients with the expansile subtype had stage I disease that was not classified as either stage IA or stage IC. One additional patient with stage I disease died from acute myeloid leukemia while free of the ovarian disease.

and one at stage IV) survived with persistent disease. One patient with a recurrence survived but with persistent disease.

In this study, 15 patients with the infiltrative subtype had stage I disease that was not classified as either stage IA or IC.
One additional patient with stage I disease died from thyroid cancer while free of the ovarian disease. In the same series, two patients with recurrent infiltrative disease (one at stage III

disease at diagnosis; in 17 to 30% of patients who appear to have stage I disease, lymph-node metastases are detected (as compared with no women with expansile mucinous ovarian cancer). Even if the cancer is diagnosed at an early stage, the prognosis for women with infiltrative mucinous ovarian cancer is much poorer, with fatal relapses reported for 15 to 30% of patients with stage I disease (Table 2). Thus, the distinction between stage I expansile and stage I infiltrative subtypes is crucial, since it may influence indications for staging lymphadenectomy or adjuvant chemotherapy.

### SURGICAL MANAGEMENT

## MANAGEMENT OF EARLY-STAGE MUCINOUS CARCINOMA

For young patients wishing to preserve their fertility, a unilateral salpingo-oophorectomy is usually proposed, with peritoneal staging procedures (cytology, peritoneal biopsies, and omentectomy). In older patients, bilateral salpingooophorectomy is preferred. The priority is to choose the best surgical approach (laparotomy or a minimally invasive laparoscopic approach) for minimizing the risk of perioperative tumor rupture. Such a rupture would alter the FIGO stage and influence both surgical and medical management of histologically confirmed mucinous ovarian cancer. Unilateral salpingo-oophorectomy is a reasonable approach in women with stage I disease who wish to preserve their fertility. The risk of recurrence is lower than that reported for women with stage I serous cancers (6% vs. 20%, P<0.001).17,40 Only one study has evaluated the results of fertility-sparing surgery in women with the expansile subtype of mucinous ovarian cancer and those with the infiltrative subtype, and the results suggest that it could be safely used for both subtypes.<sup>41</sup>

A small fraction of patients with macroscopically normal findings on surgical exploration have microscopic peritoneal spread (positive cytologic results in 5.7% of cases or microscopic involvement of the omentum or peritoneal-biopsy specimen in 1.7% of cases) or appendiceal spread (metastasis in 1.1% of cases), but peritoneal or appendiceal spread remains a rare event as compared with disease spread in other epithelial subtypes (Table S2 in the Supplementary Appendix).<sup>42,43</sup>

The rate of nodal spread is very low in cases of apparent stage I mucinous ovarian cancer (<2%).<sup>44,45</sup> However, the higher rate of nodal involvement in stage I infiltrative mucinous ovarian cancer (17 to 30%) suggests that pelvic and paraaortic lymphadenectomy should be proposed for all patients with infiltrative disease, regardless of stage, but can be safely omitted for patients with stage I expansile disease.<sup>37,42</sup>

# MANAGEMENT OF STAGE III OR IV MUCINOUS OVARIAN CANCER

The prognosis for women with stage III or IV mucinous ovarian cancer is poorer than the prognosis for women with other, more common subtypes (particularly serous or endometrioid ovarian cancer) and may be related to a poorer response to chemotherapy (Table S3 in the Supplementary Appendix). 11,16,30,46-48 Some authors have argued that this poor prognosis is due to the inherently aggressive biology of the tumor and the questionable technical feasibility of complete resection, raising doubts regarding the usefulness of an aggressive debulking surgery in women with stage III or IV mucinous ovarian cancer.<sup>13</sup> Conversely, in a series involving 50 patients with stage III or IV mucinous ovarian cancer, overall survival was increased by a factor of 3.8 among patients who underwent optimal debulking surgery.<sup>47</sup> Finally, in an analysis of three randomized trials involving 3126 patients (147 with mucinous ovarian cancer), the size of the residual disease was shown to significantly affect overall and event-free survival in a multivariate analysis of data for patients with mucinous ovarian cancer.49 In conclusion, debulking surgery with the objective of a macroscopically complete resection remains a cornerstone of management for advanced mucinous ovarian cancer.

### MEDICAL MANAGEMENT

The prognosis for women with mucinous ovarian cancer depends on the stage of disease. <sup>13,49</sup> Overall survival is higher for the majority of patients presenting with stage I disease than for those with nonmucinous histologic subtypes (hazard ratio, 0.52; 95% confidence interval [CI], 0.30 to 0.92). However, the trend is the inverse for women with stage III or IV mucinous ovarian cancer, who have significantly lower overall sur-

vival than women with nonmucinous histologic subtypes (hazard ratio, 2.81; 95% CI, 2.47 to 3.21).<sup>50</sup> Retrospective series have confirmed lower response rates to first-line platinum-based chemotherapy (mainly carboplatin and paclitaxel) among women with mucinous ovarian cancer (13 to 60%) than among women with serous ovarian cancer (64 to 87%) (Table S3 in the Supplementary Appendix).<sup>11,16,30,46-48,50</sup>

Given the histologic similarities between primary mucinous ovarian cancer and gastrointestinal carcinomas and the in vitro synergy between oxaliplatin and fluorouracil in preclinical models of mucinous ovarian cancer, empirical use of chemotherapeutic regimens that are traditionally used for gastrointestinal cancers has been tested.<sup>51,52</sup> Gynecologic Oncology Group trial 0241 (involving European, Australian, Korean, and North American groups) was designed to study the activity of a colorectal cancer regimen in women with newly diagnosed metastatic mucinous ovarian cancer. A phase 3 trial randomly assigned women to receive treatment with either paclitaxel and carboplatin (control group) or the combination of capecitabine and oxaliplatin.31 In addition, there was a secondary randomization in which women were assigned to receive bevacizumab or placebo in order to test the activity of antiangiogenesis therapy. The trial had slow accrual and was closed prematurely. Preliminary results based on the small group of patients (50) who underwent randomization showed no significant difference in progression-free survival among the treatment groups and confirmed a low objective response rate (10 of the 50 women, or 20%, had a response), regardless of the treatment regimen.31

Neoadjuvant treatment for advanced ovarian cancer has been tested in the European Organization for Research and Treatment of Cancer (EORTC) 55971 and CHORUS trials. The studies compared initial surgery with a strategy of neoadjuvant chemotherapy.<sup>53,54</sup> Patients with mucinous cancers accounted for only 1 to 3% of the patients, making it impossible to draw any conclusions.

There is a dearth of data from randomized clinical trials evaluating adjuvant chemotherapy in early-stage mucinous ovarian cancer. Various national and international guidelines provide statements about indications for adjuvant chemotherapy to help guide physicians, but these statements are not based on clear evidence of a benefit. The National Comprehensive Cancer Network (NCCN) guidelines recommend surgery alone for stage IA or IB mucinous ovarian cancer and adjuvant platinum-based chemotherapy (carboplatin and paclitaxel, or oxaliplatin with fluorouracil or capecitabine) for stage II or more advanced disease. In the case of stage IC mucinous ovarian cancer, the NCCN guidelines recommend either observation or adjuvant chemotherapy (www.nccn.org/patients/guidelines/ovarian/index .html#69/z).

Given the previously mentioned retrospective studies supporting the prognostic information provided by the growth pattern, other European guidelines have further refined treatment recommendations for stage I mucinous ovarian cancer according to the expansile versus infiltrative subtype (Fig. 2). For stage IA or IB expansile mucinous ovarian cancer, which is considered to be low risk, observation alone is recommended, whereas adjuvant chemotherapy is discussed for stage IC expansile mucinous ovarian cancer and is proposed for most cases of stage I infiltrative mucinous ovarian cancer, thus further underscoring the essential role of high-quality pathological review in the management of these rare tumors (www.ovaire-rare.org/TMRG/medecin/ adenocarcinome\_mucineux.aspx) (Fig. 2C).55

## MOLECULAR LANDSCAPE OF MUCINOUS OVARIAN CANCER AND THERAPEUTIC OPPORTUNITIES

Serous ovarian cancers lack genomic alterations in typically actionable driver oncogenes such as HER2, EGFR, ALK, and BRAF but are characterized by defects in homologous recombination DNArepair genes, such as BRCA1 or BRCA2. This deficiency in homologous recombination has been successfully exploited with the use of poly(adenosine diphosphate-ribose) polymerase (PARP) inhibitors. This drug class represents the first targeted therapy with a demonstrated clinical benefit for women who have relapsed high-grade ovarian cancer. Mucinous ovarian cancers are not associated with BRCA mutations or defects in homologous recombination, making them unlikely to benefit from PARP inhibitors. However, they frequently display mutations or amplifications that might be targetable. The most frequent alterations are KRAS mutations (in 40 to

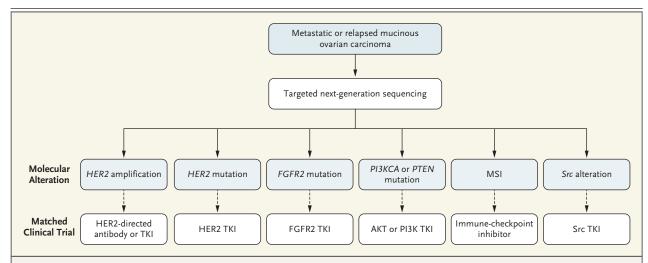


Figure 3. Proposed Individualized Investigational Approach to the Treatment of Metastatic or Relapsed Mucinous Ovarian Carcinoma. For patients with mucinous ovarian carcinoma that has metastasized or relapsed, molecular alterations identified by means of next-generation sequencing can be used to select matched treatments under investigation in clinical trials. FGFR2 denotes fibroblast growth factor receptor 2, HER2 human epidermal growth factor receptor 2, MSI microsatellite instability, PI3K phosphatidylinositol 3-kinase, and TKI tyrosine kinase inhibitor.

65% of cases), *c-MYC* amplifications (in 65%), HER2 amplifications (in 20 to 38%), and TP53 mutations (in 50 to 75%). In addition, other alterations have been identified at lower frequencies, such as homozygous deletions in *CDKN2A/B* (in 25% of cases), mutations in *PI3KCA* (in 13%), and mutations in *PTEN*, *BRAF*, *FGFR*, *KIT*, or *STK11* (in 2 to 5%).<sup>23,24,56-60</sup>

These genomic profiling studies allow mucinous ovarian cancers to be grouped into therapeutically relevant subsets (Fig. 3). For example, KRAS mutations and HER2 amplifications tend to be mutually exclusive. 23,60 The subset of HER2 (human epidermal growth factor receptor 2)positive tumors with wild-type KRAS may be particularly suited to HER2-directed therapies such as trastuzumab. Anecdotal objective responses have been described in case reports of patients with metastatic, HER2-amplified, mucinous ovarian cancer treated with either trastuzumab alone or trastuzumab combined with the oral tyrosine kinase inhibitor lapatinib.61,62 The identification of HER2 or HER3 mutations in an additional 2 to 12% of patients could justify the inclusion of such patients in basket trials of HER inhibitors.23,58

EGFR amplification or mutations in BRAF, FGFR, or STK11 have been detected in HER2-negative tumors with wild-type KRAS, suggesting that

these tumors may be responsive to inhibitors of EGFR (epidermal growth factor receptor), BRAF, FGFR2 (fibroblast growth factor receptor), or mTOR (mammalian target of rapamycin), respectively. The absence of a KRAS mutation identifies a subset of patients with colorectal cancer who are more likely to benefit from the EGFR-inhibiting antibody, cetuximab. Preclinical studies have shown that cetuximab inhibits proliferation in mucinous ovarian cancer cell lines with wild-type KRAS and in a single in vivo model, whereas it has no antitumor effect in a model of KRAS-mutated mucinous ovarian cancer.<sup>63</sup>

Most mutations in the PI3K (phosphatidylinositol 3-kinase) pathway occur with a KRAS mutation, and preclinical studies have shown synergy between MEK (mitogen-activated protein kinase) and PI3K inhibition in mucinous ovarian cancer cell lines with KRAS mutations. <sup>64</sup> Although the number of patients was small, a phase 1 trial of molecularly guided therapies for rare subtypes of ovarian cancer showed encouraging objective responses to combined MEK and PI3K inhibition in patients with KRAS-mutated ovarian cancer. <sup>65</sup>

TP53 mutations are detected at a remarkably high frequency in mucinous ovarian cancer (in 50 to 75% of cases).<sup>23,66</sup> APR-246 is a small molecule designed to restore wild-type p53 function, whereas the WEE1 inhibitor, AZD1775, abrogates

the G2-M cell-cycle checkpoint, selectively sensitizing p53-deficient cells to DNA-damaging agents.<sup>67</sup> Both agents are being investigated in

clinical trials of TP53-mutated tumors.

Finally, defects in the mismatch-repair pathway of DNA repair that result in a tumor with microsatellite instability have been detected in 15 to 20% of patients with mucinous ovarian cancer. Given that tumors with microsatellite instability have high mutation burdens and dense immune infiltrates that are characteristic of other tumor types that respond to immune-checkpoint inhibition, enthusiasm is high for testing inhibitors of PD-1 (programmed death 1) or PD-L1 (programmed death ligand 1) in the subset of mucinous ovarian cancers with microsatellite instability. The subscript of the patients of th

#### FUTURE DIRECTIONS

Important questions remain regarding the management of high-risk, localized mucinous ovarian cancer (stage I infiltrative subtype or stage IC expansile subtype). What are the criteria for selecting patients with high-risk stage I disease for adjuvant treatment? What is an ideal cytotoxic regimen? Will therapy that has some activity against gastrointestinal tumors have meaningful activity against mucinous ovarian cancer? In the future, targeted therapy may be worth testing in patients who have mucinous ovarian cancer with selected genetic alterations such as HER2 muta-

tions or microsatellite instability (Fig. 3).<sup>72,73</sup> The rarity of the tumor mandates international collaboration to evaluate new therapies in a timely fashion

In line with these questions, the Fifth Ovarian Cancer Consensus Conference of the Gynecologic Cancer InterGroup identified four key areas for further research in mucinous ovarian cancer: improvement in the histologic criteria for diagnosis, definition of the optimal surgical and medical approaches to the management of highrisk localized disease, identification of an active cytotoxic regimen, and enrollment of patients in clinical trials of new therapeutics.<sup>74</sup>

Dr. Morice reports receiving advisory board fees from Roche, lecture fees from Johnson & Johnson, and fees for participating on a board from Clovis; Dr. Gouy, receiving consulting fees from Roche; and Dr. Leary, receiving fees for serving as chief investigator or principal investigator on clinical trials, travel support paid to her institution, and advisory board fees from AstraZeneca; fees for serving as principal investigator on clinical trials, travel support paid to her institution, and advisory board fees from Clovis; travel support and advisory board fees from Tesaro; advisory board fees from Gridstone, Seattle Genetics, and Biocad; grant support paid to her institution from Merus and Inivata; fees for serving as chief investigator or principal investigator on a clinical trial paid to her institution from Roche, Pfizer, MSD, BMS, and Pharmamar; and grant support paid to her institution, fees for serving as chief investigator on a clinical trial, and advisory board fees from GamaMabs. No other potential conflict of interest relevant to this article was reported.

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# Exhibit 130

### UNITED STATES DISTRICT COURT

### DISTRICT OF SOUTH DAKOTA

### SOUTHERN DIVISION

DEANE BERG,	) CIV. 09-4179-KES
Plaintiff,	)
vs.	) MEMORANDUM OPINION ) AND ORDER
JOHNSON & JOHNSON;	)
JOHNSON & JOHNSON	)
CONSUMER COMPANIES, INC.;	)
LUZENAC AMERICA, INC.;	)
JOHN DOES/JANE DOES 1-30;	)
UNKNOWN BUSINESSES	
AND/OR CORPORATIONS A-Z,	)
	)
Defendants.	)

Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. move for summary judgment on all of plaintiff's claims (Docket 149) and also move to exclude the testimony of four of plaintiff's experts (Dockets 140, 143, 145, and 147). Defendant Luzenac America, Inc. joins in the motions (Dockets 151, 153, 155, 156, and 157). For the following reasons, defendants' motions to exclude are granted in part and denied in part.

Defendants' motion for summary judgment is denied.

### **FACTUAL BACKGROUND**

Berg was diagnosed with ovarian cancer in December of 2006. She was 49 years old at the time. Prior to her diagnosis, Berg used Johnson & Johnson products—Johnson's Baby Powder and Shower to Shower—to dust her

perineum for feminine hygiene purposes. She applied the products on a daily basis from 1975 until 2007.

Talc is one of the main ingredients in Johnson's Baby Powder and Shower to Shower. Talc is a naturally occurring mineral that is mined from the ground and used in various applications. Luzenac supplies talc to Johnson & Johnson.

Research has been ongoing studying how talc affects the female reproductive system for a number of years. For example, Dr. Daniel Cramer, one of Berg's proposed experts, published a study in 1982 that found that an association existed between the application of talc to a woman's genital area and the development of ovarian cancer. Defendants stayed current on the various studies that analyzed any potential hazards associated with talc.

Berg alleges that her application of talc to her perineum caused her ovarian cancer and brought this product liability action against defendants because their products did not include any warnings regarding the possible hazards of applying talc to a woman's perineum. Berg has identified four expert opinions in support of her claims.

First, Dr. Cramer is an epidemiologist and is prepared to testify that talc use in the genital area has a strong causal association with ovarian cancer. Further, Dr. Cramer's opinion is that Berg's frequent application of talc to her genital area was "the major cause of her invasive serous ovarian cancer[.]" Docket 148-1 at 18.

Second, Dr. Gary Rosenthal is a toxicologist and is prepared to testify about talc's immunotoxic potential and how such potential relates to ovarian cancer. His opinion is that Berg's frequent talc use "played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

Third, Dr. John Godleski is an expert in microscopy, and he examined tissues taken from Berg's reproductive system following her diagnosis of ovarian cancer. He is prepared to testify that talc particles were present in Berg's tissues.

Fourth, Dr. David R. Lenorovitz and Dr. Edward E. Karnes are experts in the field of forensic human factors and warnings. Their designation as experts is to: (1) ascertain if talc posed a hazard to the populace; (2) ascertain if any such hazard was open and obvious to a reasonable user; (3) determine if there was a feasible way to place a warning on the talc product; and (4) determine if there was a financially and technically reasonable alternative to talc. Docket 173 at 2.

### MOTIONS TO EXCLUDE EXPERT TESTIMONY

In this diversity action, federal law governs whether expert testimony is admissible. *Wagner v. Hesston Corp.*, 450 F.3d 756, 760 (8th Cir. 2006). Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012). The rule provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill,

experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. In applying Rule 702, the trial judge becomes a "gatekeeper" who screens evidence to ensure its reliability and relevance. *Russell*, 702 F.3d at 456. "The rule clearly is one of admissibility rather than exclusion." *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 448 (8th Cir. 2008). An expert's opinion should be excluded "only if it is so fundamentally unsupported that it can offer no assistance to the jury." *Id.* 

The district court applies a three-part test when screening proposed testimony for experts under Rule 702:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). To satisfy the reliability requirement, the party offering the expert testimony must show by a preponderance of the evidence "that the methodology underlying [the expert's] conclusions is scientifically valid." Barrett v. Rhodia, Inc., 606 F.3d 975, 980 (8th Cir. 2010). In making the reliability determination, the court may consider: (1) whether the theory or technique can be or has been tested; (2) whether the

theory or technique has been subjected to peer review or publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operations; and (4) whether the theory or technique is generally accepted in the scientific community. *Russell*, 702 F.3d at 456. Additional factors to consider include: "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alterative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008). "This evidentiary inquiry is meant to be flexible and fact specific, and a court should use, adapt, or reject" these factors as the particular case demands. *Russell*, 702 F.3d at 456.

When making this inquiry, the court should focus on "principles and methodology, not on the conclusions that they generate." *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993)). At times, conclusions and methodology are not entirely distinct from one another, and the court "need not completely pretermit judicial consideration of an expert's conclusions." *Id.* With these principles in mind, the court will now address defendants' motions to exclude expert testimony.

### I. Dr. Daniel Cramer

Defendants' sole argument in support of their motion to exclude

Dr. Cramer's testimony goes to the issue of whether his testimony is reliable.

Defendants attack Dr. Cramer's testimony regarding both specific causation and general causation, arguing that the testimony put forth to support each is not reliable. For purposes of defendants' motion to exclude Dr. Cramer's testimony, the court only considers whether the testimony is admissible and does not consider whether it is sufficient to prove an element in plaintiff's case.

Daubert, 509 U.S. at 596 (noting the difference between admissibility and sufficiency).

Dr. Cramer is the Professor of Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School and is a practicing obstetrician and gynecologist. He has a doctorate degree in epidemiology from the Harvard School of Public Health.

Dr. Cramer's expert report relies on epidemiology<sup>3</sup> to address two issues:

(1) "the association between use of cosmetic talc powders in the genital area and

<sup>&</sup>lt;sup>1</sup> It appears to be undisputed that Dr. Cramer is qualified to give expert testimony and that his testimony is relevant.

<sup>&</sup>lt;sup>2</sup> Sufficiency is addressed in the portion of this order dealing with defendants' motion for summary judgment.

<sup>&</sup>lt;sup>3</sup> Epidemiology is the "field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." <u>Reference Manual on Scientific Evidence</u> 551 (3d ed. 2011), *available at* 2011 WL 7724261, \*2.

ovarian cancer with regard to the likelihood that this is cause-and-effect" and (2) "the possible relevance of talc use to the occurrence of ovarian cancer in the specific case of Ms. Deane Berg[.]" Docket 148-1 at 3. The report concludes by opining that (1) there is a causal association between the use of talc and ovarian cancer, and (2) chronic talc use was the major cause of Berg's invasive serous ovarian cancer. *Id.* at 18.

Defendants make two arguments in support of their motion to exclude Dr. Cramer's testimony. First, they argue that Dr. Cramer's report is inadmissible because it fails to rule out alternative causes of Berg's cancer. Second, they argue that Dr. Cramer's report is inadmissible because the odds ratios established in the report and Dr. Cramer's interpretations of those odds ratios stem from unreliable methods.

### A. Ruling Out Alternative Causes

Defendants argue that Dr. Cramer's methodology is not reliable because he fails to rule out alternative causes of Berg's cancer. Defendants rely on these four Eighth Circuit Court of Appeals opinions to support their proposition that Dr. Cramer was required to rule out alternative causes of Berg's cancer:

Barrett, 606 F.3d 975; Bland v. Verizon Wireless, (VAW) L.L.C., 538 F.3d 893 (8th

<sup>&</sup>lt;sup>4</sup> Defendants argue extensively in their briefs that Dr. Cramer's testimony fails to establish either specific or general causation. Such arguments go to the sufficiency of Dr. Cramer's testimony and not the admissibility of it. Because a motion to exclude expert testimony is concerned only with admissibility, these arguments will not be addressed in this part of the order.

Cir. 2008); *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748 (8th Cir. 2006); and *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202 (8th Cir. 2000). None of these cases, however, require an epidemiologist to rule out all alternative causes in order for his testimony to be admissible.

In *Barrett*, the Eighth Circuit found that the district court did not abuse its discretion when it limited the expert testimony of a toxicologist and a treating physician. 606 F.3d at 981-82. The toxicologist conceded that she lacked "significant scientific knowledge underpinning [her] opinion and that she did not rule out alternative causes of [plaintiff's] injury. . . . Her opinion . . . was admittedly based on assumption, without any scientific testing or exposure analysis." *Id.* at 981. The treating physician was not allowed to testify about the cause of the plaintiff's toxic exposure because he "assumed that [plaintiff] had been injured by hydrogen sulfide gas exposure without any scientific verification and without considering any alternative causes." *Id.* at 982. Neither expert witness was offering epidemiologic evidence. Both experts had glaring deficiencies in their opinions because they failed to do any scientific verifications, relied on unsupported assumptions, and did not consider alternative causes.

In *Bland*, the Eighth Circuit found that the district court did not abuse its discretion by excluding a treating physician's expert testimony. 538 F.3d at 897-98. The treating physician intended to testify about the differential

diagnoses that he conducted. *Id.* at 897. "A differential diagnosis is a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated." *Bland*, 538 F.3d at 897. The treating physician's differential diagnosis was inadmissible because he failed to eliminate other possible causes. *Id.* The very nature of a differential diagnosis requires a consideration and elimination of other possible causes. By failing to consider other causes, a differential diagnosis cannot, by definition, be reliable. Thus, *Bland* stands for the proposition that an admissible differential diagnosis requires the expert to consider and eliminate other possible causes. *Bland* does not stand for the proposition that an expert offering epidemiologic evidence must rule out all other possible causes for his testimony to be admissible.

In *Marmo*, the Eighth Circuit found that the district court acted within the bounds of discretion when it precluded a toxicologist from testifying. 457 F.3d at 758. The toxicologist did not examine the plaintiff, did not inquire about other toxic exposures, did not exclude confounding factors, and "admitted that the causation standard she employed was not subject to expression in terms of a potential rate of error and was a much lower standard than medical causation." *Id. Marmo* does not support defendants' proposition that an expert offering epidemiologic evidence must rule out all other possible causes for his testimony to be admissible.

Lastly, in *Turner* the Eighth Circuit concluded that the district court did not abuse its discretion by excluding a treating physician's expert opinion. 229 F.3d at 1208-09. Just as in *Bland*, the treating physician's opinion was based on a differential diagnosis in which he "admitted that he made no attempt to consider all the possible causes, or to exclude each potential cause until only one remained, or to consider which of two or more non-excludable causes was the more likely to have caused the condition." *Id.* at 1208. Again, failing to properly administer a differential diagnosis resulted in an inadmissable differential diagnosis. But *Turner* does not require that an epidemiologist perform a differential diagnosis, which would require consideration of other possible causes.

After a review of these cases, the appropriate legal proposition created from these opinions is that an expert witness who performs a differential diagnosis must consider all other possible causes and exclude each potential cause until only one remains, or consider which of two or more non-excluded potential causes was the more likely to have caused the condition. Dr. Cramer, however, does not claim to have performed a differential diagnosis. Indeed, his testimony is based on epidemiology. Moreover, Dr. Cramer's report indicates that he did in fact consider other possible causes of Berg's cancer. Therefore, Dr. Cramer's opinion will not be excluded on the basis that he failed to rule out all alternative causes. *See In re Prempro Prod. Liab. Litiq.*, 586 F.3d 547, 566 (8th

Cir. 2009) (noting that an expert's "explanations as to conclusions not ruled out went to weight and not admissibility").

### B. Dr. Cramer's Methodology

Defendants' second argument goes to the general methodology applied by Dr. Cramer. In his expert report, Dr. Cramer notes that, in general, there is an odds ratio<sup>5</sup> of 1.33 between perineal talc use and ovarian cancer. Dr. Cramer further asserts that a woman with Berg's characteristics has an odds ratio of 3.53. Defendants argue that the 3.53 odds ratio established in Dr. Cramer's report comes from unreliable methods. The court begins its analysis by addressing defendants' specific concerns with Dr. Cramer's findings and then moves to a more general examination of the methodology employed by Dr. Cramer.

First, defendants claim Dr. Cramer's testimony is unreliable because it conflicts with existing scientific literature that shows the appropriate odds ratio is more in line with the 1.33 figure that Dr. Cramer generated. But there is "no requirement that published epidemiological studies supporting an expert's opinion exist in order for the opinion to be admissible." *Bonner v. ISP Tech., Inc.,* 

<sup>&</sup>lt;sup>5</sup> An odds ratio "expresses in quantitative terms the association between exposure to an agent and a disease." <u>Reference Manual on Scientific Evidence</u> 568 (3d ed. 2011), *available at* 2011 WL 7724261, \*10-\*11. Typically, if the odds ratio equals 1.0, the risk in exposed individuals is the same as the risk in unexposed individuals. *Id.* at 567. The greater the odds ratio the greater the risk in exposed individuals. *Id.* For example, an odds ratio of 4.0 indicates that the risk of disease in the exposed group is four times as high as the risk of disease in the unexposed group. *Id.* 

259 F.3d 924, 929 (8th Cir. 2001). Dr. Cramer's testimony will be admitted so long as his methodology is reliable even if his conclusions are novel. *See id.* ("The district court could not exclude scientific testimony simply because the conclusion was 'novel' if the methodology and the application of the methodology were reliable.").

Second, defendants argue that the testimony is unreliable because he "cherry-picked" data in order to form an opinion solely for purposes of litigation. "That an expert testifies based on research he has conducted independent of litigation provides important, objective proof that the research comports with the dictates of good science." Lauzon, 270 F.3d at 692. Dr. Cramer has been studying the association between talc use and ovarian cancer since at least 1982. He has published several articles on the subject over the past 30 years. While it is true that his specific findings relevant to this case were generated during the course of litigation, the methods he employed in reaching his conclusions are very similar to the methods used in his previous research. Indeed, the data he used to generate the odds ratios came mostly from his past research. The only difference between his past and present research seems to exist in how he categorized his data. Defendants label this "cherry-picking." The court views it as simply looking at the existing data from a different perspective. Therefore, the court concludes that although Dr. Cramer's opinion was

developed during the course of this litigation, the opinion "naturally flowed from [his] research." *Polski*, 538 F.3d at 839.

Third, defendants assert that the testimony is unreliable because Dr. Cramer's conclusions conflict with his non-litigation research and also conflict internally. If Dr. Cramer's previous, or even present, research contradicts his testimony in this case, certainly defendants can challenge his credibility during cross-examination. *See Kuhn*, 686 F.3d at 627 (noting that when an expert offers testimony that conflicts with his opinion, the appropriate response from the court is to allow the opposing party to challenge the credibility of the expert). But unless his methodology is unreliable, the court will not preclude his testimony.

Defendants also identify alleged inconsistencies in Dr. Cramer's findings (i.e., noting a protective effect for limited talc application). Again, this is a criticism of Dr. Cramer's results, not his methodology. Defendants will have the chance at trial during cross examination to attack his results.

The court will now analyze Dr. Cramer's methodology from a broader perspective under the seven factors articulated by the Eighth Circuit in *Polski* 

<sup>&</sup>lt;sup>6</sup> Additionally, Dr. Cramer testified that he is attempting to get his latest findings published in a scientific journal. This is important because it shows that Dr. Cramer has a stake in his findings independent from this litigation. Suspicions would arise if an expert were to propose testimony for litigation and then refuse to stand behind those findings in the scientific community. That is not the case here.

and previously set forth herein, while also addressing additional issues raised by defendants.<sup>7</sup>

As indicated in his report, Dr. Cramer performed a case-control study<sup>8</sup> to generate his final conclusions. A case-control study is commonplace in the field of epidemiology. According to Dr. Cramer, there have been nineteen *published* case-control studies addressing the talc and ovarian cancer association since 1982.<sup>9</sup> Docket 148-1 at 5, 20-21. Thus, the technique of using a case-control study to assess the association between talc use and ovarian cancer has been both tested and subjected to peer review.

Defendants are quick to note that Dr. Cramer's *specific findings* have not been tested or peer reviewed, specifically pointing to Dr. Cramer's categorization that allowed for a determination of the "[a]ssociation between genital talc use

<sup>&</sup>lt;sup>7</sup> The court has already discussed whether the expertise was developed for litigation or naturally flowed from the expert's research and found that it weighs in favor of admission. *Polski*, 538 F.3d at 839.

<sup>&</sup>lt;sup>8</sup> "In case-control studies, the researcher begins with a group of individuals who have a disease (cases) and then selects a similar group of individuals who do not have the disease (controls). The researcher then compares the groups in terms of past exposures. If a certain exposure is associated with or caused the disease, a higher proportion of past exposure among the cases than among the controls would be expected." Reference Manual on Scientific Evidence 559 (3d ed. 2011), available at 2011 WL 7724261, \*6.

<sup>&</sup>lt;sup>9</sup> In other words, the technique of using a case-control study to analyze the association between talc use and genital cancer is generally accepted in the scientific community, even if the results of Dr. Cramer's specific study are outliers.

and ovarian cancer among non-Jewish serous invasive cases and controls without a family history of ovarian or early onset breast cancer, stratified by menopausal status." Docket 148-1 at 17. This is mostly an attack on the results and not the methodology, and as a result goes to the weight to be given to the evidence and not its admissibility. Even if one were to consider defendants' argument an attack on Dr. Cramer's methodology, their argument is unpersuasive. First, although Dr. Cramer's specific categorization has not been tested, there is no reason why testing cannot occur using either Dr. Cramer's data or alternative data. Second, as discussed above, Dr. Cramer is in the process of getting his findings published. Third, and perhaps most important, Dr. Cramer's categorization was his attempt to connect his research with the facts of the case. His technique makes sense under the facts of this case because it shows the odds ratio of a woman in Berg's position.

Defendants criticize Dr. Cramer's choice to exclude menopausal, non-Jewish women who do not have a history of ovarian or early onset breast cancer. But as Dr. Cramer explains, this decision was made because Berg is not Jewish, was premenopausal at the time of her diagnosis, and did not have a history of ovarian or early onset breast cancer.

Moreover, Dr. Cramer's categorization is also a recognition of alternative causes of ovarian cancer. As Dr. Cramer points out in his report, women who are Jewish or have a history of breast or ovarian cancer are at an increased risk

for ovarian cancer. Berg is neither Jewish nor has a history, family or personal, of breast or ovarian cancer. Additionally, she tested negative for the full panel of BRCA1 and BRCA2 mutations—additional factors that increase one's risk for ovarian cancer.

Lastly, defendants argue that Dr. Cramer's theory of biological plausibility<sup>10</sup> is unreliable, making his ultimate conclusions equally as unreliable. Dr. Cramer's two models of biological plausibility. One model relies on the assertion that talc induces inflammation, down regulates immunity, and enhances ovarian tumor development. The second model theorizes that talc's inflammatory properties lead to dysregulation of immunity that would otherwise help suppress cancerous cells. Defendants assert that neither of these models has been proven. But defendants have not shown that either model is undoubtedly incorrect. In epidemiology, the "saliency of [biological plausibility] varies depending on the extent of scientific knowledge about the cellular and subcellular mechanisms through which the disease process works." Reference

Manual on Scientific Evidence 605 (3d ed. 2011), available at 2011 WL

7724261, \*30. At times, "mechanism explanations are merely
hypothesized—although hypotheses are sometimes accepted" in showing

<sup>&</sup>lt;sup>10</sup> Biological plausibility is the "[c]onsideration of existing knowledge about human biology and disease pathology to provide a judgment about the plausibility that an agent causes a disease." <u>Reference Manual on Scientific Evidence</u> 620 (3d ed. 2011), *available at* 2011 WL 7724261, \*38.

exposure can cause a disease. *Id.* Furthermore, Berg's toxicologist expert, Dr. Rosenthal, is prepared to offer additional support for Dr. Cramer's models of biological plausibility. Thus, Dr. Cramer's biological plausibility models are not so fundamentally unsupported that they fail to assist the jury. *Sappington*, 512 F.3d at 448.

After a careful review of the record, the court concludes that Dr. Cramer's expert testimony is reliable. Defendants can certainly attack his testimony at trial. *See Kuhn*, 686 F.3d at 625 ("Vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). But his testimony will not be precluded based on the arguments that defendants put forward.

### II. Dr. Gary Rosenthal

Dr. Rosenthal is prepared to offer expert testimony on the issue of "whether talc can be considered an immunotoxic<sup>11</sup> agent and the relevance of this to the biological plausibility of talc as an agent capable of causing ovarian cancer." Docket 144-1 at 3. Defendants argue that Dr. Rosenthal is not qualified to offer his expert opinion and that his opinion is unreliable.<sup>12</sup>

<sup>&</sup>lt;sup>11</sup> Immunotoxicology is a "branch of toxicology concerned with the effects of toxic agents on the immune system." <u>Reference Manual on Scientific</u> Evidence 682 (3d ed. 2011), *available at* 2011 WL 7724262, \*27.

<sup>&</sup>lt;sup>12</sup> The court assumes, for purposes of this motion, that Dr. Rosenthal's testimony is relevant.

### A. Qualifications

"A witness can be qualified as an expert by knowledge, skill, experience, training or education, and it is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in this case." Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc., 254 F.3d 706, 715 (8th Cir. 2011) (internal quotations omitted). "The relative skill or knowledge of an expert goes to the weight of that witness's testimony, not its admissibility." Loudermill v. Dow Chemical Co., 863 F.2d 566, 569 (8th Cir. 1988).

Dr. Rosenthal received his Ph.D. in environmental medicine from New York University. He has been certified as a toxicologist by the American Board of Toxicology since 1990. His research includes the study of the toxicity of various agents on the immune system, including mineral dusts. He has also studied causative and preventative measures of inflammation and cancer.

Defendants argue that because Dr. Rosenthal has no experience specifically with talc or ovarian cancer, he is not qualified. Such a narrow view of an expert's qualifications is not required under Rule 702. "Rule 702 only requires that an expert possess knowledge, skill, experience, training, or education sufficient to 'assist' the trier of fact, which is satisfied where expert testimony advances the trier of fact's understanding to any degree." *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal quotations

omitted). Dr. Rosenthal has experience studying the toxicity of mineral dust on the immune system. His expert testimony addresses whether talc can be considered an immunotoxic agent. Further, Dr. Rosenthal has experience studying the causative and preventative measures of inflammation and cancer. His expert testimony also addresses the biological plausibility of talc as an agent capable of causing ovarian cancer. Thus, the court finds that Dr. Rosenthal's qualifications are sufficient to assist the trier of fact in deciding the issues in this case.

### B. Reliability

Dr. Rosenthal's expert report offers the following conclusions: (1) talc has immunotoxic<sup>13</sup> potential; (2) it is biologically plausible that talc-mediated neoplastic events<sup>14</sup> can be evoked through various mechanisms; (3) talc can translocate from the vagina, cervix, or fallopian tube to the ovary; (4) it is biologically plausible that Berg's daily talc use for over 30 years led to chronic inflammation in target tissues; (5) neoplastic events related to chronic inflammation and/or immune modulation would likely have been elicited in

<sup>&</sup>lt;sup>13</sup> Immunotoxic means that the agent in question exerts toxicity toward the immune system or its components.

<sup>&</sup>lt;sup>14</sup> A neoplastic event is a pathologic process that results in the formation and growth of abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth cease. <u>Stedman's Medical Dictionary</u> 1288 (28th ed. 2006).

Berg; and (6) the foregoing would have played a role in disease processes leading to Berg's ovarian cancer. Docket 144-1 at 11.

Defendants argue that Dr. Rosenthal's biologically plausible opinions are merely speculative, untested, and unreliable. An examination of Dr. Rosenthal's methods is required to determine whether defendants' arguments have merit.

In reaching his conclusions, Dr. Rosenthal first addresses talc's physicochemical aspects. Docket 144-1 at 5. He asserts that talc's "poorly-soluble particulate nature" is significant because it allows talc "to be taken up by cells of the immune system . . . and transported to other parts of the body[.]" *Id.* He notes that talc shares this property with "other members of the mineral dust family, including silicates and asbestos." *Id.* He further notes that "an extensive literature exists showing that similar to asbestos and other mineral dusts, exposure to talc can result in cellular toxicity." *Id.* (citing published studies).

Dr. Rosenthal next addresses the biological evidence that supports his conclusions. He first asserts that the immune consequences of talc being "taken up" by cells "depends on the fate(s) of the cell and the engulfed talc particle." *Id.* at 6. Some fates result in the recruitment of other immune cells (because the body recognizes talc as a foreign particle) while others lead to an injury that

causes unique structures such as Giant cells<sup>15</sup> and granulomas.<sup>16</sup> *Id.* (citing published studies that show Giant cells and granulomas have been seen in response to talc exposure). Alternatively, the talc particle may be taken up by cells through the process of endocytosis.<sup>17</sup> Any of these "fates" may "play some part in the response to mineral dust deposition on mucosal surface and would be associated with measures of inflammation[.]" *Id.* at 7. Dr. Rosenthal notes that several "studies show markers of inflammation following talc exposure, including intravaginal delivery." *Id.* (citing several published articles).

To further support his opinions, Dr. Rosenthal discusses studies that show how talc can affect the immune system. He notes several studies that show talc induces granulomas in a variety of different organs. He then cites an animal study that found talc-induced granulomas resulted in deficient cellular immune functions that "have been noted to precede cancer in man." *Id.* at 7. After discussing additional studies, Dr. Rosenthal generalizes that talc causes

<sup>&</sup>lt;sup>15</sup> Giant cells granuloma is a "nonneoplastic lesion characterized by a proliferation of granulation tissue containing numerous multinucleated giant cells[.]" <u>Stedman's Medical Dictionary</u> 832 (28th ed. 2006).

<sup>&</sup>lt;sup>16</sup> Granuloma is a "[t]erm applied to nodular inflammatory lesions[.]" Stedman's Medical Dictionary 831 (28th ed. 2006). "Granuloma formation is a special type of immune response to foreign agents, where the body produces a collection of immune and related cells in an attempt to wall off a foreign agent that has resisted digestion." Docket 144-1 at 7.

<sup>&</sup>lt;sup>17</sup> Endocytosis is the "[i]nternalization of substances from the extracellular environment through the formation of vesicles formed from the plasma membrane." Stedman's Medical Dictionary 640 (28th ed. 2006).

two biologic responses—immune system suppression and inflammation—both of which have been found to be associated with cancer. *Id.* at 8-10. Moreover, he notes that the "intimate relationship between talc, inflammation, phagocytic cells,<sup>18</sup> and ovary-derived chemotactic factors<sup>19</sup> provides a mechanistic connection for talc translocation to the ovary where it can alter tissue homeostasis." *Id.* at 9.

To summarize, Dr. Rosenthal's report essentially provides that talc particles that are applied in the perineal area can move to the ovaries where they can be problematic for immune cells by causing chronic inflammation and/or immunity suppression. Chronic inflammation and immunity suppression have been shown to play roles in disease processes that lead to cancer. Based on Berg's thirty-plus years of perineal exposure to talc, it is likely that she would have experienced such chronic inflammation and/or immunity suppression in her ovaries, thus playing a "role in disease processes leading to her ovarian cancer." *Id.* at 11. Dr. Rosenthal relied on several published scientific articles as well as his own experience in immunotoxicology to form his conclusions.

<sup>&</sup>lt;sup>18</sup> Phagocytic cells are cells that can ingest bacteria, foreign particles, and other cells. Stedman's Medical Dictionary 1470 (28th ed. 2006).

<sup>&</sup>lt;sup>19</sup> Chemotactic factors are factors that cause movement of cells in response to chemicals, whereby the cells are attracted or repelled by substances exhibiting chemical properties. <u>Stedman's Medical Dictionary</u> 358 (28th ed. 2006).

Defendants attack Dr. Rosenthal's opinion from several perspectives. First, defendants challenge Dr. Rosenthal's comparison of talc with other mineral dusts, arguing that he is not qualified to discuss the relevant properties of the three mineral dusts. The main assertion that Dr. Rosenthal makes, however, is that talc, asbestos, and silica all have poorly-soluble particulate natures that encourage uptake by immune cells. It is this property, he opines, that would cause the three mineral dusts to act similar from an immunotoxicology perspective. See, e.g., Reference Manual on Scientific Evidence 664 (3d ed. 2011) (noting toxicologists often compare the structures of different compounds to infer toxicity). Dr. Rosenthal only relies on one physical property that the three substances share. Defendants urge the court to require Dr. Rosenthal to be an expert on all physicochemical properties of each substance if he is to compare any of them. Such expansive expertise, however, is not required. If defendants have issue with the factual basis for his comparisons, they are welcome to challenge it at trial, but such a challenge goes to the weight to be given to the evidence, not its admissibility. Bonner, 259 F.3d at 929 ("[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.").

Second, defendants argue that Dr. Rosenthal's reference to historic accounts of asbestos in cosmetic talc is unreliable. Regardless of its reliability, the court finds this part of Dr. Rosenthal's opinion to be irrelevant. Berg has not

alleged that asbestos was in the talc that allegedly caused her ovarian cancer. Instead, she argues that the talc itself caused her ovarian cancer. Thus, any reference to historic accounts of asbestos in cosmetic talc is irrelevant and is also likely to confuse the jury. As a result, Dr. Rosenthal is precluded from testifying about historic accounts of asbestos in cosmetic talc.

Third, defendants take issue with Dr. Rosenthal's assertions relating to cellular toxicity. The general crux of defendants' arguments deal with the factual basis of the opinion and not the methodology. Further, defendants misinterpret Dr. Rosenthal's opinion. When disputing Dr. Rosenthal's claim that talc causes cellular toxicity, defendants argue that cellular toxicity is a general term not necessarily related to cancer. Nowhere in Dr. Rosenthal's expert report does he make the assertion that all cellular toxicity causes cancer. Thus, defendants' argument lacks merit.

Fourth, defendants argue that Dr. Rosenthal's references to metallic components in talc make his entire opinion unreliable, noting his deposition testimony in which he states that the "combination of these compounds together in the context of talc have not been studied in a detailed way[.]" Docket 144-2 at 14. The court agrees that Dr. Rosenthal's reference that he "would not completely dismiss a potential role for contaminating immunotoxic metals" is an unreliable statement because Dr. Rosenthal did not provide an adequate basis in science to support it. Nevertheless, this statement is a small part of his

report and has little or nothing to do with the rest of his expert opinion. Thus, his references to metallic components do not make his entire opinion unreliable.

Fifth, defendants attack Dr. Rosenthal's efforts to show biologic plausibility. They argue that because Berg's tissues did not indicate that the specific mechanisms that Dr. Rosenthal offered were present, his testimony is irrelevant.<sup>20</sup> The court disagrees and finds that Dr. Rosenthal's offering of mechanisms that provide biologic plausibility to Berg's claim that talc caused her ovarian cancer are relevant.<sup>21</sup>

Sixth, defendants argue that Dr. Rosenthal's opinion should be excluded because of his word choices in his report. The court will not entertain such a meritless objection.

Defendants' seventh challenge is similar to its third. They argue that because one of the mechanisms (TNF-alpha<sup>22</sup>) that Dr. Rosenthal offers has not been conclusively proven to cause cancer, it is unreliable. This again misstates Dr. Rosenthal's report. The report asserts that talc has been shown to cause

<sup>&</sup>lt;sup>20</sup> Defendants' argument goes to the sufficiency of specific causation rather than admissibility. This argument is more properly addressed as part of the motion for summary judgment.

<sup>&</sup>lt;sup>21</sup> If defendants had conclusive proof that the mechanisms were not present, then such testimony would likely be irrelevant.

<sup>&</sup>lt;sup>22</sup> TNF-alpha stands for tumor necrosis alpha, which is a pleiotropic cytokine synthesized widely throughout the female reproductive tract. Stedman's Medical Dictionary 698 (28th ed. 2006).

inflammation through an increase in TNF-alpha. The report does not state that TNF-alpha causes cancer—the basis for defendants' challenge.

Defendants' eighth challenge attacks the factual basis for Dr. Rosenthal's opinion. First, they argue that one of the studies he relied on is a case report. But their citation to *Glastetter v. Novartis Pharmaceuticals Corporation*, 252 F.3d 986 (8th Cir. 2001), is not dispositive. *Glastetter* simply states that "causal attribution based on case studies must be regarded with caution." 252 F.3d at 990. Here, Dr. Rosenthal is not using case studies as the entire foundation for his opinions, but just as one piece of the puzzle. Further, defendants argue that Dr. Rosenthal's admission that there is a scientific debate about whether talc is immunosuppresive precludes his testimony. This admission does not make his opinion unreliable. *See Kuhn*, 686 F.3d at 625 ("Proponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered to determine which of several competing scientific theories has the best provenance.") (internal quotation omitted).

Defendants' ninth challenge is not actually a challenge at all. Instead, defendants simply reference various statements made by Dr. Rosenthal in relation to Dr. Cramer's theories.

Tenth, defendants take issue with Dr. Rosenthal's proffer that the immunosuppressive effects of asbestos may contribute to malignancy by decreasing natural killer cells. Dr. Rosenthal offers this statement to support

his conclusion that substances that have immunosuppressive effects play a role in the disease processes leading up to cancer development. He does not assert, as defendants suggest, that talc exposure decreases natural killer cells. Again, defendants' misstatement of Dr. Rosenthal's opinion makes their objection meritless.

Defendants' eleventh challenge shares many of the shortcomings as their previous challenges. Defendants muddle sufficiency with admissibility, arguing that Berg's medical records did not show evidence of inflammation and thus any theory of inflammation is irrelevant. They challenge the factual basis of Dr. Rosenthal's opinion, claiming his interpretation of various animal studies makes his opinion unreliable. Lastly, they take Dr. Rosenthal's reluctance to definitively state that talc exposure causes ovarian cancer to mean that his opinions are speculative and unreliable. Dr. Rosenthal's report, however, does not assert that talc exposure causes ovarian cancer. Instead, Dr. Rosenthal's report states that Berg's talc exposure "would have played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

In summary, the court finds that the majority of defendants' challenges to Dr. Rosenthal's expert testimony are unpersuasive. In making his ultimate conclusions, Dr. Rosenthal relied on his own expertise in the field of toxicology, his past research, and several other published scientific studies. Any gaps or limitations in Dr. Rosenthal's reasoning can be presented to the jury. *See Kuhn*,

686 F.3d at 632 ("The studies' limitations may be presented to the jury, and [the expert's] reliance on the studies may be tested through the traditional means of cross examination and presentation of contrary evidence."). Indeed, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

#### III. Dr. John Godleski

Dr. Godleski reviewed histopathological<sup>23</sup> slides taken from Berg following her diagnosis of ovarian cancer using advanced microscopic methodologies. In his review of twenty-six slides, Dr. Godleski found three particles of talc. He asserts that his findings indicate that talc was present in Berg's ovary tumor. Dr. Godleski opines that the talc found in Berg's tissues "is evidence for a causal link between the presence of talc and the development of [her] ovarian cancer." Docket 141-1 at 4.

Defendants argue that Dr. Godleski is unqualified and that his opinions are irrelevant and unreliable.

#### A. Qualifications

Dr. Godleski is the head of Pulmonary Pathology at Brigham and
Women's Hospital, a major teaching hospital of Harvard Medical School. He also

<sup>&</sup>lt;sup>23</sup> Histopathology is the science or study dealing with the cytologic and histologic structure of abnormal or diseased tissue. <u>Stedman's Medical</u> Dictionary 893 (28th ed. 2006).

leads a research group at the Harvard School of Public Health. He earned his medical degree from the University of Pittsburgh School of Medicine where he did research using electron microscopy. He has published more than 140 papers related to pulmonary pathology including a number using analytical electron microscopy. He is a "recognized expert whose opinion is sought by pathologists from other hospitals in the diagnosis of foreign material in tissues throughout the body using scanning electron microscopy and energy dispersive X-ray analyses." Docket 141-1 at 2.

Defendants note that Dr. Godleski's background does not include determining the causes of ovarian cancer. They argue that Dr. Godleski has done limited research on the relationship between talc and ovarian cancer, that his knowledge of the causes of ovarian cancer is limited, and that he is not an epidemiologist. On the other hand, defendants do not dispute that Dr. Godleski is an expert at identifying foreign particles in human tissue. Because his testimony is limited to identifying foreign particles in human tissue, the court finds he is qualified to offer his expert opinion.

#### B. Relevancy

Defendants argue that Dr. Godleski's opinions are irrelevant because he cannot tie the talc particles found in Berg's tissues to defendants' products.

This argument goes to the sufficiency of the testimony, not the relevancy of it.

Berg claims that talc from defendants' products caused her ovarian cancer.

Certainly, testimony that establishes that talc particles were found in Berg's ovary tumor is relevant to this case.

#### C. Reliability

Defendants' reliability arguments are based on a mischaracterization of Dr. Godleski's expert opinion. Their arguments suggest that Dr. Godleski is opining that the talc particles he found caused Berg's ovarian cancer. Dr. Godleski's opinion stops well short of such a conclusion. His report notes that "the talc found in this case is evidence for a causal link between the presence of talc and the development of [Berg's] ovarian cancer." Docket 141-1 at 4. His opinion merely states the obvious: the talc found in Berg's tissues is evidence in this case.

Defendants again argue that Dr. Godleski is required to rule out alternative causes. Because Dr. Godleski is not opining that talc was the cause of Berg's ovarian cancer through a differential diagnosis, he need not rule out other potential causes of her cancer. The fact that he found particles other than talc goes to the sufficiency of his testimony. The remainder of defendants' arguments are based on their mischaracterization of Dr. Godleski's opinions and will not be addressed. Therefore, Dr. Godleski's expert testimony will not be excluded.

#### IV. Dr. David R. Lenorovitz and Dr. Edward E. Karnes

Dr. Lenorovitz and Dr. Karnes are prepared to provide expert testimony "addressing certain forensic human factors and warnings issues."<sup>24</sup> Docket 146-3 at 3. Defendants argue that the expert report goes far beyond the boundaries applicable to human factors experts. In addition, defendants argue that any proposed testimony that is related to human factors is unreliable.

#### A. Qualifications

The court begins its evaluation by addressing the experts' qualifications. Dr. Lenorovitz has 44 years of professional experience as a human factors engineer, ergonomist, and cognitive psychologist. He received his Ph.D. in human factors engineering from the State University of New York and is certified as a professional ergonomist by the Board of Certification in Professional Ergonomics. He has spent the last six years as a forensic human factors consultant with a special emphasis on warnings systems design, development, and warnings adequacy evaluation.

Dr. Karnes has 50 years of professional experience as a human factors professional. He received his Ph.D. in experimental psychology from Temple University and is board-certified. He has served as a human factors consultant for plaintiffs and defendants in several different legal cases. The majority of his

<sup>&</sup>lt;sup>24</sup> According to Berg, forensic human factors and warnings is the "multidisciplinary field examining how humans interact with the world around them." Docket 173 at 1.

research has concerned the development of warnings and user understanding of safety issues associated with the use of consumer and industrial products.

Both experts are qualified to render an expert opinion within their field.

#### B. Defendants' Challenges

Defendants first take issue with any attempt by the experts to offer testimony regarding defendants' intent as well as testimony regarding defendants' purported lobbying efforts. See, e.g., Docket 146-3 at 14 ("The defendants have knowingly decided to ignore the hazard present in their products."); Docket 146-3 at 5 ("The defendants collaborated and joined forces with other 'talc-interested parties' to pool resources and fund . . . programs intended to . . . defeat any research study[.]"). Both Dr. Karnes and Dr. Lenorovitz admit that the basis for their opinions about defendants' intent and lobbying efforts comes from "reading the documents that were provided." Docket 146-2 at 20; 22. "Where the subject matter is within the knowledge or experience of lay people, expert testimony is superfluous." Ellis v. Miller Oil Purchasing Co., 738 F.2d 269, 270 (8th Cir. 1984). There is no reason why the jury cannot review the same documents and form their own opinions about defendants' intent and lobbying efforts. Thus, Drs. Karnes and Lenorovitz are precluded from offering an expert opinion about defendants' intent or lobbying efforts because such testimony would be superfluous.

Next, defendants seek to preclude Drs. Karnes and Lenorovitz from testifying about any legal conclusions, e.g., any duties that defendants owed to Berg. Under South Dakota law, whether a duty exists is a question of law. *Bland v. Davison Cnty*, 507 N.W.2d 80, 81 (S.D. 1993). Any expert testimony on a legal conclusion will not assist the trier of fact and is thus inadmissible. *United States v. Wells*, 63 F.3d 745, 753 (8th Cir. 1995) ("[I]nstruction on the law is the function of the court, not a defense expert."), *rev'd on other grounds*, 519 U.S. 482 (1997); *Peterson v. City of Plymouth*, 60 F.3d 469, 475 (8th Cir. 1995) ("The legal conclusions were for the court to make. It was an abuse of discretion to allow the testimony."). Thus, Drs. Karnes and Lenorovitz are precluded from testifying about any duties or responsibilities that defendants allegedly owed to Berg.

Defendants also move the court to preclude any testimony Drs. Karnes and Lenorovitz may offer that is outside their expertise, such as the medical risks of ovarian cancer, whether talc is hazardous, and whether there is a feasible alternative product. "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 702. Thus, Drs. Karnes and Lenorovitz can form their opinions based on the testimony of other experts in this case. But Drs. Karnes and Lenorovitz cannot make unsupported statements that are outside of their field of expertise. *See Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003) (noting that

the district court did not abuse its discretion in deciding that an expert could not testify about matters outside of his expertise). In addition, the court need not admit cumulative evidence. Fed. R. Evid. 403. Any detailed description of testimony provided by Berg's other experts regarding the medical risks of ovarian cancer, whether talc is hazardous, and whether there is a feasible alternative product would certainly be cumulative because Drs. Karnes and Lenorovitz are not capable of offering their novel opinions in such areas as they are not qualified to do so. Therefore, the testimony of Drs. Karnes and Lenorovitz regarding these areas must be limited. For purposes of their testimony, Drs. Karnes and Lenorovitz may only "assume" that ovarian cancer has medical risks, talc is hazardous, and there is a feasible alternative product. They cannot, however, go into detail on any of these subjects.

More generally, Berg asserts that Drs. Karnes and Lenorovitz were designated (1) to ascertain if talc posed a hazard to the populace; (2) to determine whether the hazard was open and obvious to a reasonable user; (3) to determine if there was a feasible way to place a warning on the talc product; and (4) to determine if there was a financially and technically reasonable alternative to talc. Docket 173 at 2. As discussed above, Drs. Karnes and

<sup>&</sup>lt;sup>25</sup> This assumes that plaintiff will present evidence that there is a feasible alternative product.

Lenorovitz are not qualified to provide an opinion on whether talc is hazardous to the populace or whether there is a financially reasonable alternative to talc.

Moreover, Drs. Karnes and Lenorovitz cannot assist the jury on the issue of whether the alleged hazard was open and obvious to a reasonable user. The basis for Drs. Karnes and Lenorovitz concluding that the alleged hazard was not open and obvious is based solely on the fact that Berg, Dr. Karnes, and Dr. Lenorovitz were not aware of the hazard prior to this litigation. A jury can rely on its own common sense and experiences in forming its conclusion on whether the alleged hazard was open and obvious.

Therefore, the testimony of Drs. Karnes and Lenorovitz will be limited to whether there was a feasible way to place a warning on defendants' products.<sup>26</sup> The court will now turn to defendants' summary judgment motion.

#### SUMMARY JUDGMENT LEGAL STANDARD

Summary judgment is appropriate if the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party can meet this burden by presenting evidence that there is no dispute of material fact or that the nonmoving party has not presented evidence to support an element of her

<sup>&</sup>lt;sup>26</sup> After reviewing the remainder of the report in light of the extensive limitations discussed above, the court finds that any additional proposed testimony outside of the issue of placing a warning on the product is not admissible because it is either cumulative or outside the expertise of Drs. Karnes and Lenorovitz.

case on which she bears the ultimate burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). "The nonmoving party may not 'rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial.' " *Mosley v. City of Northwoods, Mo.*, 415 F.3d 908, 910 (8th Cir. 2005) (quoting *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995)).

Summary judgment is precluded if there is a dispute in facts that could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). For purposes of a summary judgment motion, the court views the facts and the inferences drawn from such facts "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

Because this is a diversity action, the court applies the law of the state in which it sits. *Prudential Ins. Co. of Am. v. Kamrath*, 475 F.3d 920, 924 (8th Cir. 2007). Thus, South Dakota law applies to Berg's claims.<sup>27</sup>

#### **ANALYSIS**

Defendants move for summary judgment on three grounds: (1) Berg's experts do not present admissible evidence of causation and have failed to rule out other potential causes; (2) there is no evidence that would impose upon

 $<sup>^{27}</sup>$  The parties do not dispute that South Dakota law applies.

defendants a duty to warn; and (3) Berg cannot demonstrate that defendants' failure to warn caused her ovarian cancer.

#### I. Evidence of Causation

Defendants argue that Berg has not presented admissible evidence of causation and thus all of her claims must fail. To survive summary judgment, Berg must present evidence beyond unsupported conclusions and speculative statements that defendants' products caused her injuries. *Burley v. Kytec Innovative Sports Equip., Inc.*, 737 N.W.2d 397, 407-10 (S.D. 2007). Expert testimony is ordinarily required to establish causation in a products liability action, particularly in a toxic tort action. *Id.*; *see also Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010) ("To succeed in her claims, [plaintiff] needed to present expert testimony showing that the [substance] could have caused [the] injuries and that it did in fact cause those injuries.").

The majority of defendants' arguments rely on the assumption that the court would grant their motions to exclude expert testimony analyzed above. But because the court found that the majority of the expert testimony offered by Berg is admissible, most of defendants' arguments are moot. The court will nonetheless evaluate the admissible evidence that Berg has put forth to ensure that she has met her burden of creating a genuine issue of fact on the causation element.

As a preliminary matter, Berg asserts, and defendants do not dispute, that she began using talc in her genital area in 1975. She claims that the talc came from defendants' products—"Johnson's Baby Powder" and "Shower to Shower"—and that her use continued until 2007. It is undisputed that Berg was diagnosed with ovarian cancer in December of 2006.

Berg has put forth admissible expert testimony to support her claim that defendants' products caused her ovarian cancer. First, Dr. Cramer, an epidemiologist, opines generally that talc use in the genital area has a strong causal association with ovarian cancer. *See Glastetter*, 252 F.3d at 992 (noting that epidemiological evidence can assist in establishing causation). He goes further to opine that Berg's frequent application of talc to her genital area was "the major cause of her invasive serous ovarian cancer[.]" Docket 148-1 at 18. In forming his opinions, Dr. Cramer relied on various facts: Berg was premenopausal when she was diagnosed; she has no personal or family history of breast or ovarian cancer; she is not Jewish; she tested negative for the full panel of BRCA1 and BRCA2 mutations; and the odds ratio for someone with similar characteristics is 3.53.

Second, Dr. Rosenthal, a toxicologist, provides biologic plausibility to Dr. Cramer's opinions. *See Marmo*, 457 F.3d at 758 ("[A] toxicologist may testify that exposure to a chemical caused a person's symptoms and injuries."). He asserts that talc has immunotoxic potential and can evoke neoplastic events,

which may lead to ovarian cancer. Further, he claims that it is biologically plausible that Berg's frequent application of talc led to chronic inflammation and/or immune modulation of tissues and cells in her ovaries. Thus, he concludes that Berg's frequent genital application of talc "played a role in disease processes leading to her ovarian cancer." Docket 144-1 at 11.

Third, Dr. Godleski, an expert in microscopy, provides evidence that talc was actually present in the tissues that were removed from Berg's ovaries and fallopian tubes following her diagnosis. Lastly, Berg claims that had she known of any dangers involved in applying talc to her genital area, she would not have done so.

Defendants urge the court to grant summary judgment because Berg has not ruled out other potential causes of her ovarian cancer. But Berg is not required to "eliminate all other possible explanations of causation[.]" *Burley*, 737 N.W.2d at 407. She needs only to "set forth sufficient evidence establishing a causal connection between the [defendants' product] and the resulting injury." *Id.* The court finds that she has done so here. Determining the weight of the evidence Berg has put forth is an issue for the jury.

#### II. Duty to Warn

Defendants argue that Berg cannot move forward with her failure to warn claims because she has not established the existence of a duty to warn. The

court must separate Berg's failure to warn claims to address defendants' argument.

#### A. Strict Liability Failure to Warn

Defendants argue that they did not owe Berg a duty to warn because their product is not dangerous. "The issue under strict liability is whether the manufacturer's failure to adequately warn rendered the product unreasonably dangerous without regard to the reasonableness of the failure to warn judged by negligence standards." *Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 912 (S.D. 1987). "[K]nowledge of the potential risk is imputed to the manufacturer." *Id.* Thus, defendants cannot defend "on grounds that, at the time of production, [they] neither knew nor could have known of the risk." *Id.* Thus, if Berg can establish at trial that a "danger existed associated with a foreseeable use of [defendants'] product," the duty to warn element is automatically satisfied for purposes of her strict liability failure to warn claim. *Burley*, 737 N.W.2d at 409.

#### B. Negligent Failure to Warn

To establish liability for negligent failure to warn, Berg must show, among other things, that defendants "knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner." *Id.* at 410. Defendants argue that there was and still is no duty to warn because there lacks any substantial evidence that

their products are dangerous. Additionally, defendants argue that any evidence that Berg puts forth that allegedly shows dangers associated with defendants' products falls short of creating a duty to warn.

Defendants' arguments are premature at this time. Defendants are correct in stating that under South Dakota law "the existence of a duty is a question of law to be determined by the court." Janis v. Nash Finch Co., 780 N.W.2d 497, 500 (S.D. 2010). But in a negligent failure to warn case, whether defendants owed Berg a duty to warn depends, first, on whether defendants' products are unreasonably dangerous. See Burley, 737 N.W.2d at 410 (requiring plaintiff to show that the "manufacturer knew or reasonably should have known that the product was dangerous"). Indeed, if defendants' products are not dangerous, no warning would be necessary. Whether defendants' products are unreasonably dangerous is a factual determination for the jury. See Peterson, 400 N.W.2d at 914 ("[I]ssues of reasonableness and foreseeability . . . are usually jury issues."). Thus, the court cannot make its legal determination of whether a duty existed until the jury has the opportunity to determine if the products are dangerous. See Reiss v. Komatsu America Corp., 735 F. Supp. 2d 1125, 1146 (D.N.D. 2010) ("The existence of a duty to warn is generally a preliminary question of law for the court, but if the existence of a duty depends

upon factual determinations, their resolution must be resolved by the trier of fact.").<sup>28</sup>

#### III. Proximate Cause

Defendants also argue that Berg has failed to put forth sufficient facts to show that defendants' failure to warn was the legal cause of her ovarian cancer. Defendants' argument raises the issue of when the duty to warn arose. They claim that even if a duty to warn exists, such duty arose much later than 1975—the year Berg began dusting her perineum with talc. Thus, defendants argue, Berg cannot prove that defendants' failure to warn was the legal cause of her cancer because the duty did not arise in time to prevent her cancer.

As discussed above, Berg's strict liability claim does not necessitate the finding that a duty existed. Moreover, the issue of *whether* a duty ever existed must first be determined in order to ascertain *when* such a duty arose. Even so, Berg has put forth evidence that defendants were aware of the alleged dangers of talc as early as 1971. Thus, there is a material issue of fact as to whether defendants "knew or reasonably should have known that the product was dangerous" as far back as 1971. *See Burley*, 737 N.W.2d at 410.

<sup>&</sup>lt;sup>28</sup> Defendants' reliance on *Brech v. J.C. Penney Co.*, 698 F.2d 332, 334 (8th Cir. 1983), in support of their assertion that federal standards are relevant in determining if a duty to warn existed is misplaced. In review of District Court Judge Nichol's factual findings from a bench trial, the Eighth Circuit stated that "[a]lthough evidence that the gown surpassed federal standards is not necessarily conclusive proof that the garment was not *unreasonably dangerous*, it is nevertheless evidence which the court can consider on the issue." *Id.* (emphasis added).

In summary, Berg has put forth sufficient, admissible evidence to show that there exists genuine issues of material fact. Also, the court is unable to determine whether defendants owed Berg a duty to warn at this time. Thus, defendants' motion for summary judgment is denied.

#### CONCLUSION

Dr. Cramer's expert opinion is admissible because it was the product of reliable methodologies, and he was not required, as an epidemiologist, to rule out all alternative causes of Berg's ovarian cancer. The majority of Dr. Rosenthal's opinions are admissible because he is qualified to render such opinions, and he used reliable methodologies in forming his opinions.

Dr. Godleski's opinion is admissible because he is qualified, and the opinion is relevant and stems from reliable methodologies. Lastly, Dr. Lenorovitz and Dr. Karnes, as human factors experts, can only testify on the limited issue of whether there was a feasible way to place a warning on defendants' products.

Moreover, Berg has put forth sufficient evidence to show that there exists genuine issues of material fact that preclude summary judgment. Furthermore, the court is unable to determine whether defendants owed Berg a duty to warn at this time. Accordingly, it is

ORDERED that defendants' motion to exclude the testimony of Dr. Godleski (Dockets 140 & 153) is denied.

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IT IS FURTHER ORDERED that defendants' motion to exclude the

testimony of Dr. Rosenthal (Dockets 143 & 156) is granted in part and denied in

part.

IT IS FURTHER ORDERED that defendants' motion to exclude the

testimony of Dr. Lenorovitz and Dr. Karnes (Dockets 145 & 155) is granted in

part and denied in part.

IT IS FURTHER ORDERED that defendants' motion to exclude the

testimony of Dr. Cramer (Docket 147 & 151) is denied.

IT IS FURTHER ORDERED that defendants' motion for summary

judgment (Docket 149) is denied.

Dated April 12, 2013.

BY THE COURT:

/s/ Karen E. Schreier

44

KAREN E. SCHREIER

UNITED STATES DISTRICT JUDGE

## Exhibit 131

## IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS STATE OF MISSOURI

MICHAEL BLAES on behalf of SHAWN BLAES, Deceased, SAVANNA CREWS on behalf of ANGELA DAWN HERSHMAN, Deceased, DARLENE EVANS on behalf of ERON EVANS, Deceased,	Cause No. 1422-CC09326-01  Division 10
Plaintiffs,	FILED
v.	JUN 1 2 2017
JOHNSON & JOHNSON, et al.,	) 22ND JUDICIAL CIRCUIT ) CIRCUIT CLERK'S OFFICE BY DEPUTY
Defendants.	

#### <u>ORDER</u>

This cause is now before the Court on: (1) Motions for Summary Judgment filed by Defendant Johnson & Johnson & Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.; and (2) Motions to Exclude the Testimony of Dr. Colditz, Dr. Cramer, Dr. Godleski, Dr. Ness, Dr. Omiecinski, Dr. Siemiatychi, Dr. Plunkett, Dr. Rosenthal, Dr. Chobanian and Mr. Steinberg filed by Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.; and (3) Defendant Johnson & Johnson, Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc. Motions to Transfer Venue or Continue the June 5, 2017 Trial Date Based on Jury Pool Taint.

The Court now rules as follows:

Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.'s, Motions for Summary Judgment are **DENIED**.

Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer, Inc. and Defendant Imerys Talc America, Inc.'s Motions to Exclude the Testimony of Dr. Colditz, Dr.

JUN 12 201/ TSJ

### Case 3:16-md-02738-MAS-RLS Document 9895-3 Filed 05/30/19 Page 60 of 565 PageID: 71304

Cramer, Dr. Godleski, Dr. Ness, Dr. Omiecinski, Dr. Siemiatychi, Dr. Plunkett, Dr. Rosenthal, Dr. Chobanian and Mr. Steinberg are **DENIED**.

Defendant Johnson & Johnson and Defendant Johnson & Johnson Consumer, Inc.'s and Defendant Imerys Talc America, Inc.'s Motions to Transfer Venue or Continue the June 5, 2017 Trial Date Based on Jury Pool Taint is **DENIED**.

**SO ORDERED:** 

Rex M. Burlison Circuit Judge Division 10

Dated: 6/12/2017

## Exhibit 132

State Court of Fulton County
Case 3:16-md-02738-MAS-RLS Document 9895-3 Filed 05/30/19 Page 62 of 565 PageIDE-FILED\*\*
71306 71306 3/26/2019 2:04 PM
LeNora Ponzo, Clerk
Civil Division

### IN THE STATE COURT OF FULTON COUNTY STATE OF GEORGIA

ANASTASIA BROWER, a minor, through her	)	
legal guardian PAMELA RUSSELL, and	)	
PAMELA RUSSELL, as the Executrix of the	)	
Estate of Diane Brower, deceased,	)	
Plaintiff,	)	
	)	CIVIL ACTION FILE
v.	)	NO. 16-EV-005534-E
	)	
JOHNSON & JOHNSON, INC.; JOHNSON &	)	
JOHNSON CONSUMER COMPANIES, INC.;	)	
and IMERYS TALC AMERICA, INC.,	)	
Defendants.	)	

## ORDER ON JOHNSON DEFENDANTS' MOTIONS TO EXCLUDE THE TESTIMONY OF DR. JAMES BARTER, DR. LAURA PLUNKETT, AND DR. JOHN GODLESKI

The matter is before the Court on Defendant Johnson & Johnson, Inc., and Johnson & Johnson Consumer Companies, Inc.'s ("Johnson Defendants") motions to exclude the expert testimony of various witnesses, filed on October 30, 2019.<sup>1</sup> Plaintiff filed responses in opposition to the motions to exclude on November 29, 2018.

#### The *Daubert* Standard

Trial courts act as gatekeepers in assessing an expert witness' qualifications to testify and the relevancy and reliability of that expert's testimony. Kumho Tire Co. v. Carmicheal, 526 U.S. 137, 141 (1999). Motions to exclude testimony of an expert witness are properly granted "where there is no circumstance under which the evidence under scrutiny is likely to be admissible at trial." Shiver v. Ga. & Fla. Railnet, Inc., 287 Ga. App. 828, 829 (2007) (quoting Gwinnett Co. v. Howington, 280 Ga. App. 347 (2006)). Expert scientific or technical testimony is admissible only if it is both relevant and reliable. Kumho Tire Co., at 137. The test for determining the reliability of expert testimony is flexible and the *Daubert* factors, such as testing, peer review, error rates, and

<sup>&</sup>lt;sup>1</sup> While the motion was filed by the Defendants, Defendant Imerys Talc America, Inc., filed a notice of bankruptcy on February 13, 2019 and this Court entered an order reserving rulings on all pending motions filed by Defendant Imerys Talc America, Inc.

acceptability within relevant scientific or technical communities, "neither necessarily nor exclusively appl[y] to all experts or in every case." <u>Id.</u>, at 142.

The determination of whether a witness is qualified to render an opinion as an expert is a legal determination for the trial court and is not disturbed by reviewing courts absent an abuse of discretion. HNTB Ga., Inc., v. Hamilton-King, 287 Ga. 641, 642 (2010); Yount v. State, 249 Ga. App. 563, 565 (2001). In considering the admissibility of expert testimony, a trial court should first consider whether the factors are reasonable measures of reliability in a given case before evaluating proffered expert testimony. Kumho Tire Co., at 152. The Georgia Court of Appeals has identified the "two methods by which [a] plaintiff in a chemical exposure case may show specific causation in a manner that satisfies the *Daubert* standard: (1) 'dose/response relationship' or 'threshold phenomenon; and (2) 'differential diagnosis.'" Shiver v. Ga. & Fla. Railnet, Inc., 287 Ga. App. 828 (2007)(quoting Hardyman v. Norfolk & Western R. Co., 243 F3d 225, 263 (2001)). In Hardyman, the Sixth Circuit Court of Appeals noted that Plaintiff's expert testified that "one simply could not quantify the level or dose of risk factors causative of [carpal tunnel syndrome] in a manner consistent with a dose/response relationship or threshold level." Hardyman, at 262. The Hardyman Court likened carpal tunnel syndrome and its unknown dose/response relationship with exposure to toxic substances:

while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation.

<u>Hardyman</u>, at 265-66(quoting <u>Westberry v. Gislaved Bummi AB</u>, 178 F.3d 257, 264 (4<sup>th</sup> Cir. 1999).

Finally, a critical distinction exists between the admissibility of expert testimony and its credibility as determined by the trier of fact: "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." <u>Daubert v. Merrell Dow Pharmaceuticals, Inc.</u>, 509 U.S. 579, 596 (1993).

#### Dr. James Barter

Defendant moves the Court to limit the expert testimony of Dr. James Barter on the grounds that he failed to rule in Ms. Brower's use of Johnson & Johnson as a possible cause of her ovarian cancer and his failure to rule out other risk factors associated with cancer. Defendant's contentions go to the credibility of his testimony, not its admissibility. <u>Daubert</u>, *supra*. Accordingly, based upon review of the record and applicable law cited above, Defendants' motion to exclude the testimony of Dr. James Barter is DENIED.

#### Dr. Laura Plunkett

Defendant moves the Court to limit the expert testimony of Dr. Laura Plunkett on the basis that she does not have the requisite experience to testify about the causes of ovarian cancer, has never been a business executive or manager of product safety for a cosmetics company, and does not have legal training. A review of the record indicates that Dr. Plunkett has significant experience as a board certified pharmacologist and toxicologist. Accordingly, based upon the record as a whole and applicable law cited above, Defendants' motion to exclude the testimony of Dr. Laura Plunkett is DENIED.

#### Dr. John Godleski

Defendant moves the Court to exclude the expert testimony of Dr. John Godleski on the basis that his report fails to identify the methodology relied on in his conclusion. A review of the record indicates that Dr. Godleski's report details his methodology sufficiently in his report. Accordingly, based upon the record as a whole and applicable law cited above, Defendants' motion to exclude the testimony of Dr. John Godleski is DENIED.

SO ORDERED this 26th day of March, 2019.

Jane Morrison, Judge

**FULTON COUNTY STATE COURT** 

Copies to Counsel via E-File Georgia.

## Exhibit 134

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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY  TO STATE JOHNSON & JOHNSON   MDL No.  TALCUM POWDER PRODUCTS   16-2738 (FLW)(LHG)  MARKETING SALES PRACTICES,   AND PRODUCTS LIABILITY     LITIGATION     THIS DOCUMENT RELATES TO     ALL CASES      VOLUME II  VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT PERSONAL CARE PRODUCTS COUNCIL by and through its Designated Representative,  LINDA LORETZ, Ph.D.  WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018 9:09 A.M.  Reported by: Leslie A. Todd		Page 379
IN RE JOHNSON & JOHNSON ) MDL NO.  TALCUM POWDER PRODUCTS ) 16-2738 (FLW)(LHG)  MARKETING SALES PRACTICES, )  AND PRODUCTS LIABILITY )  LITIGATION )  THIS DOCUMENT RELATES TO )  ALL CASES )	UNITED STATES DIS	TRICT COURT
IN RE JOHNSON & JOHNSON ) MDL No.  TALCUM POWDER PRODUCTS ) 16-2738 (FLW)(LHG)  MARKETING SALES PRACTICES, )  AND PRODUCTS LIABILITY )  LITIGATION )  THIS DOCUMENT RELATES TO )  ALL CASES ) X  VOLUME II  VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT PERSONAL CARE PRODUCTS COUNCIL by and through its Designated Representative,  LINDA LORETZ, Ph.D.  WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018  9:09 A.M.	DISTRICT OF NEW	JERSEY
IN RE JOHNSON & JOHNSON ) MDL No.  TALCUM POWDER PRODUCTS ) 16-2738 (FLW)(LHG)  MARKETING SALES PRACTICES, )  AND PRODUCTS LIABILITY )  LITIGATION )  THIS DOCUMENT RELATES TO )  ALL CASES )  VOLUME II  VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT PERSONAL CARE PRODUCTS COUNCIL by and through its Designated Representative,  LINDA LORETZ, Ph.D.  WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018  9:09 A.M.		
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AND PRODUCTS LIABILITY )  LITIGATION )  THIS DOCUMENT RELATES TO )  ALL CASES )   V O L U M E I I  VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT PERSONAL CARE PRODUCTS COUNCIL by and through its Designated Representative,  LINDA LORETZ, Ph.D.  WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018  9:09 A.M.	TALCUM POWDER PRODUCTS	) 16-2738 (FLW)(LHG)
LITIGATION  )  THIS DOCUMENT RELATES TO  ALL CASES  VOLUME II  VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT PERSONAL CARE PRODUCTS COUNCIL by and through its Designated Representative,  LINDA LORETZ, Ph.D.  WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018  9:09 A.M.	MARKETING SALES PRACTICES,	)
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by and through its Designated Representative,  LINDA LORETZ, Ph.D.  WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018  9:09 A.M.		
WASHINGTON, D.C.  MONDAY, OCTOBER 1, 2018  9:09 A.M.		
MONDAY, OCTOBER 1, 2018 9:09 A.M.	LINDA LORETZ,	Ph.D.
9:09 A.M.	WASHINGTON, D	O.C.
	MONDAY, OCTOBER 1	, 2018
Reported by: Leslie A. Todd	9:09 A.M.	
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<u>-</u>	Reported by: Leslie A. Todd	

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Linda Loretz, Ph.D.

	Page 380		Page 382
1	Deposition of LINDA LORETZ, Ph.D., held at the	1	APPEARANCES (CONTINUED):
2	offices of:	2	ATTEMATICES (CONTINUED).
3	511 <b>66</b> 5 511	3	MICHELLE A. PARFITT, ESQUIRE
4		4	ASHCRAFT & GEREL, LLP
5	SEYFARTH SHAW LLP	5	4900 Seminary Road, Suite 650
6	975 F Street, N.W.	6	Alexandria, Virginia 22311
7	Washington, DC 20004	7	(703) 997-1774
8	<i>5</i> ,	8	(1.1.2)
9		9	NICHOLAS J. KOHRS, ESQUIRE
10		10	LUNDY, LUNDY, SOILEAU & SOUTH, LLP
11		11	501 Broad Street
12	Pursuant to notice, before Leslie Anne Todd,	12	Lake Charles, Louisiana 70601
13	Court Reporter and Notary Public in and for the	13	(337) 439-0707
14	District of Columbia, who officiated in	14	
15	administering the oath to the witness.	15	ON BEHALF OF PCPC AND THE WITNESS:
16	-	16	THOMAS T. LOCKE, ESQUIRE
17		17	SEYFARTH SHAW LLP
18		18	975 F Street, NW
19		19	Washington, DC 20004
20		20	(202) 463-2400
21		21	
22		22	
23		23	
24		24	
25		25	
	Page 381		Page 383
1	APPEARANCES	1	APPEARANCES (CONTINUED):
2		2	
3	ON BEHALF OF THE PLAINTIFFS:	3	ON BEHALF OF JOHNSON & JOHNSON DEFENDANTS:
4	CHRISTOPHER V. TISI, ESQUIRE	4	KATHLEEN FRAZIER, ESQUIRE
5	LEVIN PAPANTONIO THOMAS MITCHELL	5	SHOOK, HARDY & BACON, LLP
6	RAFFERTY & PROCTOR, PA	6	600 Travis Street
7	316 S. Baylen Street, Suite 600	7	Suite 3400
8	Pensacola, Florida 32502	8	Houston, Texas 77002-2926
9	(850) 436-6250	9	(713) 227-8008
10		10	
11	RICHARD M. GOLOMB, ESQUIRE	11	ON BEHALF OF THE IMERYS DEFENDANTS:
12	BENJAMIN ISSER, ESQUIRE	12	JONATHAN F. DONATH, ESQUIRE
13	GOLOMB & HONIK, P.C.	13	COUGHLIN DUFFY, LLP
14	1835 Market Street, Suite 2900	14	350 Mount Kemble Avenue
15	Philadelphia, Pennsylvania 19103	15	Morristown, New Jersey 07962
16	(215) 985-9177	16	(973) 267-0058
17	TED ME A DOWN TO STATE	17	CAMPEDDE OF AVEN ECONOMI
	TED MEADOWS, ESQUIRE	18	CATHERINE SLAVIN, ESQUIRE
18	, ,	١ , ,	
19	P. LEIGH O'DELL, ESQUIRE	19	GORDON & REES SCULLY MANSUKHANI, LLP
19 20	P. LEIGH O'DELL, ESQUIRE RYAN BEATTIE, ESQUIRE	20	Three Logan Square
19 20 21	P. LEIGH O'DELL, ESQUIRE RYAN BEATTIE, ESQUIRE BEASLEY, ALLEN, CROW, METHVIN, PORTIS &	20 21	Three Logan Square 1717 Arch Street, Suite 610
19 20 21 22	P. LEIGH O'DELL, ESQUIRE RYAN BEATTIE, ESQUIRE BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.	20 21 22	Three Logan Square 1717 Arch Street, Suite 610 Philadelphia, Pennsylvania 19103
19 20 21 22 23	P. LEIGH O'DELL, ESQUIRE RYAN BEATTIE, ESQUIRE BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. 218 Commerce Street	20 21 22 23	Three Logan Square 1717 Arch Street, Suite 610
19 20 21 22	P. LEIGH O'DELL, ESQUIRE RYAN BEATTIE, ESQUIRE BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.	20 21 22	Three Logan Square 1717 Arch Street, Suite 610 Philadelphia, Pennsylvania 19103

2 (Pages 380 to 383)

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Linda Loretz, Ph.D.

	Page 384	Page	386
1	APPEARANCES (CONTINUED):	1 EXHIBITS	
2	, , , , , , , , , , , , , , , , , , , ,	2 (Attached to transcript)	
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7	Suite 6950	7 No. 47 Draft Minutes Talc Interest Party	
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10		No. 48 Letter to Mary Wolfe from CTFA,	
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13	KATIE TUCKER (Paralegal - Beasley Allen)	13 Bates MUSCAT000004007 to 000004013	470
14	EMILY H. MANOSO, Staff Counsel, PCPC	No. 50 E-mail re Rothman Proposal for	
15	THOMAS F. MYERS, Staff Counsel, PCPC	15 Updating CTFA Submission of Comments	
16		to the NTP, Bates JNJ 000391715 to	
17	DANIEL HOLMSTOCK (Videographer)	17 000391716 474	
18	JONATHAN VADERS (Technical Support)	No. 51 Article entitled "Use of cosmetic	
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4 (Pages 388 to 391)

Linda Loretz, Ph.D.

	Page 392		Page 394
1	PROCEEDINGS	1	A Yes.
2		2	Q Okay. And a 30(b)(6) deposition, just
3	THE VIDEOGRAPHER: The time is 9:09 a.m.	3	to get rid of all the legalese there, is a
4	on October 1st, 2018. This is video 1, Volume II,	4	deposition where the company puts forward a
5	in the continued deposition of Dr. Linda Loretz.	5	witness to testify on behalf of the company.
6	A reminder to the witness, she is still	6	You understand that?
7	under oath.	7	A Yes.
8	CROSS-EXAMINATION	8	Q And you understand that your testimony
9	BY MR. TISI:	9	is binding on the company?
10	Q Good morning, Dr. Loretz.	10	A Yes.
11	A Good morning.	11	Q Okay. And you're speaking not only as
12	Q Just to remind the jury, what is	12	Dr. Loretz, but you're speaking on behalf of the
13	please state your name, please.	13	Personal Care Products Council?
14	A Linda Loretz.	14	A Yes.
15	Q Okay. And you are a toxicologist?	15	Q And by the Personal Care Products
16	A Yes.	16	Council, you understand that we also mean an
17	Q Okay. And you're here represented by	17	organization called CTFA?
18	counsel?	18	A Correct.
19	A Yes.	19	
20	Q My name is Chris Tisi. I represent	20	Q Okay. And that's the predecessor name for the Personal Care Products Council, and I
21	women with ovarian cancer who claim that talcum	21	•
22	powder products like Johnson & Johnson baby powder	22	guess it was the Cosmetic Toiletry and Fragrance
23	and Shower to Shower powder caused or contributed	23	A Association.
24	to their ovarian cancer.	24	
25	Do you understand that?	25	Q Association, correct? A Correct.
	<u>`</u>	23	
1	Page 393		Page 395
1 2	A Yes.	1	Q Yeah. And you understand your testimony
		ا م	
	Q Okay. And by the terms "talcum powder	2	is also binding on them as well?
3	products," you understand that I mean cosmetic	3	is also binding on them as well?  A Yes.
3 4	products," you understand that I mean cosmetic talc used in those products?	3 4	is also binding on them as well?  A Yes.  Q Okay. You also understand that you are
3 4 5	products," you understand that I mean cosmetic talc used in those products?  A Yes.	3 4 5	is also binding on them as well?  A Yes.  Q Okay. You also understand that you are under oath, and your testimony testimony may be
3 4 5 6	products," you understand that I mean cosmetic talc used in those products?  A Yes.  Q Okay. And if I had a bottle of either	3 4 5 6	is also binding on them as well?  A Yes.  Q Okay. You also understand that you are under oath, and your testimony testimony may be played for the court or jury to consider amongst
3 4 5 6 7	products," you understand that I mean cosmetic talc used in those products?  A Yes.  Q Okay. And if I had a bottle of either Shower to Shower here or Johnson's Baby Powder,	3 4 5 6 7	is also binding on them as well?  A Yes.  Q Okay. You also understand that you are under oath, and your testimony testimony may be played for the court or jury to consider amongst all the other evidence in the case?
3 4 5 6 7 8	products," you understand that I mean cosmetic talc used in those products?  A Yes.  Q Okay. And if I had a bottle of either Shower to Shower here or Johnson's Baby Powder, what I'm referring to is everything that's in the	3 4 5 6 7 8	is also binding on them as well?  A Yes.  Q Okay. You also understand that you are under oath, and your testimony testimony may be played for the court or jury to consider amongst all the other evidence in the case?  A I do.
3 4 5 6 7 8 9	products," you understand that I mean cosmetic talc used in those products?  A Yes.  Q Okay. And if I had a bottle of either Shower to Shower here or Johnson's Baby Powder, what I'm referring to is everything that's in the bottle.	3 4 5 6 7 8 9	is also binding on them as well?  A Yes.  Q Okay. You also understand that you are under oath, and your testimony testimony may be played for the court or jury to consider amongst all the other evidence in the case?  A I do.  Q Okay. I'm going to hand you what I
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Page 396 Page 398 1 put your counsel aside for a moment -- any other 1 not prepared to testify to today as -- fully? 2 either employees, current or former employees, of 2 A Categories, I would say no. 3 3 Personal Care Products Council? Q Okay. Now, I'm going to ask you some 4 A No, just counsel. Just my counsel 4 questions today relating to specific categories, 5 5 and -and I'll list them. 6 6 Q Have you spoken to any third-party 1(e), which is dissemination of medical 7 witnesses in this case, people -- for example, 7 and scientific information on talcum powder and 8 employees of Johnson & Johnson, employees of -- of 8 ovarian cancer, 1(f), 1(g), 4(a), 4(c), and 9 Imerys, outside researchers? 9 categories 8 through 22. 10 10 A Not about this case, no. I'm just doing that for the record, but 11 Q Okay. What additional work have you 11 broadly they fall into two broad categories, and I'm going to separate my questions to you into two 12 done to prepare yourself or further prepare 12 13 yourself to testify to the topics contained in 13 broad categories. Okay? 14 that notice of deposition? 14 A Okay. 15 A I met with my attorney for several days 15 Q And the broad categories are this: 16 reviewing records, minutes, e-mails, documents 16 Communications with the Food and Drug 17 related. 17 Administration about talcum power products and 18 Q Have you spoken to John Bailey at all? 18 ovarian cancer, including, for example, the 19 19 Citizen's Petition issue. A No. 20 Q Have you spoken to John Bailey at all 20 A Okay. 21 since -- you know who John Bailey is? 21 Q Okay? 22 A Yes. 22 A Yes. 23 Q Have you spoken to John Bailey at all 23 Q The one area that I will not cover that 24 since -- at any time in this process, including 24 will be covered by one of my colleagues is the CIR 25 before your first deposition? 25 report. Page 397 Page 399 1 1 A Okav. A No. 2 Have you spoken to any lawyers not your 2 So you won't hear CIR from me. 3 3 But other than that, the communications own? 4 A The PCPC lawyers, Tom Myers and Emily 4 with the FDA will be issues I'll be asking you 5 Manoso, but beyond that, no. 5 about. 6 Q Okay. Have you reviewed the notice of 6 A Okay. 7 deposition that I placed before you, Exhibit 7 Q The second part of it is -- will be 8 No. 1, to refamiliarize yourself with the topics 8 about consultants and studies, people with whom 9 we're here to discuss today? 9 you consulted and studies that were performed or 10 A I've reviewed it before. I haven't 10 not performed at the direction of or with the 11 reviewed it very, very recently, but --11 cooperation with PCPC. 12 Q Okay. Is there any topic or topics in 12 A Okay. 13 that notice for which you have been designated 13 Q Okay. So just broadly speaking, the two 14 that you do not feel comfortable testifying to 14 categories are communications with FDA except for 15 today? In other words, that you are not -- your 15 CIR, and consultants and -- and studies. 16 investigation is not complete and you don't have 16 A Okay. Q Okay? 17 information about the topics. 17 18 A I mean, I guess I would just note that 18 A Yes. 19 obviously I wasn't here in the '80s, so I can only 19 Q All right. So let's get started. 20 go by the records that I have seen. But beyond 20 I want to talk about first 21 21 that, no. communications with the FDA, and I'd like to use 22 Q I guess what I'm asking you, and this is 22 as kind of a fulcrum of our discussions the 23 a process that is a little bit of a give and take 23 Citizen's Petition, and you know what I mean by 24 between you and me, and I -- I just want to ask 24 the "Citizen's Petition"? 25 you, are there any categories there that you're A Yes.

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Page 400 Page 402 Q Okay. To help us really understand 1 1 A 2006, no? 2 this, I prepared a timeline --2 O 2006. Excuse me. 3 MR. LOCKE: Counsel, can I just ask, I 3 Yes. A 4 mean there were a number of Citizen's Petitions. 4 O Yeah. And the Cancer Coalition 5 Can you --5 Prevention citizens filed with the FDA, and that's 6 6 in 2008. MR. TISI: I'm going to be clear. 7 MR. LOCKE: Okay. 7 A Yes. 8 MR. TISI: I'm giving a timeline here, 8 Q Okay. And there were other things. Those are already on the chart. You agree with 9 and we'll --9 10 10 MR. LOCKE: Okay. those? 11 MR. TISI: -- we'll do that. 11 A Yes. Q Okay. Let's talk for a moment what your 12 BY MR. TISI: 12 13 Q So to begin, I'm going to start with the 13 understanding -- first of all, in the course of most recent Citizen's Petition, the one that was your work with the PCPC, have you had occasions to 14 14 15 15 deal with Citizen's Petitions before, or is this filed in 2008. 16 16 the only time that this happened? A Yes, mm-hmm. 17 17 Q And you're familiar with that, correct? A Before this, this was probably the first 18 18 one. I mean we -- we filed a Citizen's Petitions A Yes. 19 19 O And to help us understand the context in ourselves that came after this. Nothing to do 20 which that Citizen's Petition was filed and what 20 with talc. 21 it is, and we haven't explained it to the jury yet 21 Q Right. And so you're familiar with the 22 and we will, I've prepared a little bit of a 22 process? timeline here. And we're going to kind of mark 23 2.3 A Yes. 24 some things so that everybody understands the 24 Q Okay. So would you tell the members of 25 historical context in which that petition was 25 the jury a little bit about what a Citizen's Page 401 Page 403 1 actually filed. 1 Petition is to the best of your understanding. 2 And I'm going to give a copy to counsel, 2 A It's -- it's --3 and we're going to hopefully fill this out 3 MR. LOCKE: Objection. 4 THE WITNESS: It's going to be a very together, and you correct me if I'm wrong on 4 5 any -- on anything I write on here. 5 simple thing, because I -- I --6 And we're going to mark this as Exhibit 6 BY MR. TISI: 7 7 Q Simple is -- simple is always better. No. 41. 8 8 A -- I have a lot of details. I mean (Exhibit No. 41 was marked for 9 identification.) 9 it's -- it's -- someone can petition FDA to 10 10 request something through a process. I believe BY MR. TISI: 11 Q And we may come back to this during the 11 the process is probably spelled out in the Code of 12 course -- back and forth to this during the 12 Federal Regulations. They can request something 13 to FDA, and then FDA has, I believe, an obligation deposition, so I'm going to ask you to kind of --13 14 we'll kind of put it aside and bring it back and 14 to respond within a certain amount of time, 15 all that. 15 although they can -- they can respond by saying 16 And just for the members of the jury, 16 we've gotten it and we're reviewing it, and then we've marked on here, we started with 1994, and they need to eventually respond to it. 17 17 18 there's a reason why I've done that, which will 18 Q And are there opportunities for other 19 become apparent, and then there's the National interested parties to file comments to that 19 petition? 20 Toxicology Program 10th Report on Carcinogens 20 21 21 that's in the year 2000. A Yes. 22 You know what I'm talking about? 22 Q Okay. And PCPC has on occasion actually 23 23 filed Citizen's Petitions themselves. 24 24 A Yes. Q Okay. The IARC review which was 2005. 25 Correct? 25 Q And we're aware that the -- a Citizen's

7 (Pages 400 to 403)

Petition was filed by a group called the Cancer Prevention Coalition seeking a cancer warning on cosmetic tale products in 2008. Correct?  4 A Yes. 5 Q Okay. And that was actually filed 6 that was actually filed in May of 2008? 7 A I don't remember. 8 Q Okay. Let's see if I can help you here. 9 (Exhibit No. 42 was marked for identification). 11 BY MR. TISI: 12 Q I'm going to hand you what I've had marked as Exhibit No. 42. 13 marked as Exhibit No. 42. 14 Do you recognize this? 15 A Yes. 16 Q Okay. Is this the Citizen's is this a Cliteria Petition that was filed on behalf of the Cancer Prevention Coalition with the Food and Drug Administration in on May 13th, 2008? 20 A That's what it looks to be, yes. 21 Q Okay. And you're familiar with that 22 document? 22 document? 23 A Yes. 24 Q And 25 MR. TISI: 3 Q The document in front of you, it was filed by a Dr. Epstein, or you know that? 4 filed by a Dr. Epstein. Do you know that? 5 A Yes. 6 Q Has anyone with PCPC ever sought to meet with Dr. Epstein, if you know? 8 A Not that I'm aware. 9 Q And he was a professor of occupational and environmental medicine at the University of Illinois Chicago Medical Center. That's in the itime is 9:23 a.m., we're going off the record? 1 the Tile VIDEOGRAPHER: The time is 9:27 a.m., and we're back on the record. 18 BY MR. TISI: 20 Q Just to reask the question, if you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 at the first paragraph, this Dr. Epstein in you look 2 a		Page 404		Page 406
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25 occupational and environmental medicine, 25 Q Okay. And starting in 1982, that issue	17 18 19 20 21 22 23	the record.  (Technical difficulties.)  THE VIDEOGRAPHER: The time is 9:27 a.m., and we're back on the record.  BY MR. TISI:  Q Just to reask the question, if you look at the first paragraph, this Dr. Epstein	18 19 20 21 22 23	Q And, Dr. Loretz, I'm sorry for the technical difficulties we're having here. I took the break to write down what I think we agreed.  Beginning in about 1982, concerns were raised that talcum powder products may cause or contribute to ovarian cancer; is that correct?

8 (Pages 404 to 407)

Page 408 Page 410 1 was an issue that was one that wasn't just one 1 Q Okay. So taking off your hat of 2 that was raised and forgotten, it was an issue 2 Dr. Loretz and putting on your hat as Personal 3 3 Care Products Council, can you tell us when the that was persistently discussed in the medical and scientific literature from that point forward. 4 4 Personal Care Products Council first became aware 5 5 Fair? of this petition? 6 6 A I'm sure it was soon after it was filed. A Yes. 7 Q Okay. So it was discussed in the '80s, 7 Q So it was filed in May of 2008. It 8 8 '90s, 2000s, and in fact, it's still being would have been approximately May of 2008. 9 discussed today. 9 A Yes. I believe so. 10 10 A Yes. Q All right. Let's put that aside for a 11 Q And by 2008, which would have been about 11 moment. We'll come back to that. 12 20 -- two decades plus since those initial 12 Now, in July of 2009, did the Personal 13 reports, the Cancer Prevention Coalition filed a 13 Care Products Council file a white paper with the 14 14 petition to the FDA that asked the FDA to mandate, FDA or comments with the FDA opposing the Cancer require, that all talcum powder products have some profession -- Prevention Coalition petition? 15 15 16 kind of warning for ovarian cancer. True? 16 A Yes. 17 A That's what the petition says, yes. 17 Q And that was filed on July 21st, 2009. 18 Q Okay. And so if you go to page 2 of the 18 Correct? 19 19 A I don't recall. letter. 20 MR. TISI: Can you please go back? 20 Q Let me see if I can provide you with 21 BY MR. TISI: 21 what I have marked as Exhibit No. 43. 22 22 (Exhibit No. 43 was marked for Q Section A, it says: "Agency action 23 requested," and point number 1, it says: 23 identification.) 24 "Immediately require cosmetic talcum powder 2.4 BY MR. TISI: 25 products to bear labels with a prominent warning 25 Q Is that the PCPC -- I'm sorry. Page 409 Page 411 1 1 Is this the response of the Personal such as 'Frequent talc application in the female 2 genital area is responsible for major risks of 2 Care Products Council to the Epstein petition to 3 ovarian cancer." 3 add a warning? 4 4 Do you see that? A Yes. 5 5 Q Okay. Now, is it fair to say, and if A Yes. 6 Q Did I read that correctly? 6 you go to the -- the position of the Personal Care 7 7 A That's what it says. Products Council is the addition of a warning 8 8 Q Okay. And Dr. Epstein also asked to be label on products such as Johnson & Johnson's baby 9 heard by the FDA on this petition, correct? 9 powder and Shower to Shower would be inappropriate 10 10 and unnecessary? A That's what it says, yes. 11 11 Q Okay. So not only did he file a letter A You're reading that somewhere? 12 requesting that the -- a warning be added to 12 Q It's the very last -- second to last 13 13 talcum powder products, but he also wanted to meet paragraph at the end. 14 with them, correct? 14 A Yes. 15 A That's what it says, yes. 15 Q And so just to make sure that we're kind 16 Q All right. You became -- the Personal 16 of 2000 -- at 30,000 feet, the petition was filed 17 17 Care Products Council became aware of this asking for a warning. The petition of the Personal Care Products Council was no warning was 18 petition -- do you remember when it became aware 18 19 19 of this petition? necessary. 20 20 A I really don't. A That's correct. 21 Q Okay. Do you remember the circumstances 21 Q In this petition did the Personal Care 22 22 under which it became aware of this petition? Products Council lay out the standard for when a 23 A I don't remember the details, no. I'm 23 warning is appropriate, if you know? 24 24 A I believe our response to the petition sure it was -- I'm sure it was soon after it was 25 filed, but I don't remember the details. 25 was to look at the science on talcum powder and

Page 412 Page 414 1 ovarian cancer. 1 Loretz. You're speaking here as a -- as the 2 Q Okay. But the question that I asked is 2 organization. 3 3 a different one. A Okay. 4 The standard of when a warning is 4 Q And the organization is responding to a 5 required is a standard that you're familiar with? 5 request to add a warning. Right? 6 A That sounds more like a legal concept, 6 A Yes. 7 so I'm not sure that I am. 7 Q And the -- presumably -- I mean, maybe I 8 8 Q Well, does the Personal Care Products should ask you the question: Did PCPC consult 9 with the requirements for adding a warning before 9 Council provide a labeling manual for its members? 10 10 A We do, but it's -- it's -- yes, it's a responding to this petition? 11 summary of existing labeling requirements, 11 MR. LOCKE: Objection. regulatory requirements. 12 THE WITNESS: I -- I mean, we don't 12 13 Q Right. Does this petition --13 agree with the petitioner's rationale for adding a 14 Dr. Epstein asked for a label to be added, 14 warning. 15 15 BY MR. TISI: correct? 16 16 MR. LOCKE: Objection. Q I understand you -- you have a difference in the weight of the evidence that 17 THE WITNESS: Yes. 17 18 18 would support or not support a warning. BY MR. TISI: My question is, did you understand at 19 Q And this opposes the addition of a 19 the time the standard for what -- what would 20 label, correct? 20 21 MR. LOCKE: Objection. 21 require a warning or not? 22 THE WITNESS: Yes. 22 MR. LOCKE: Objection. 23 THE WITNESS: I think it was our 23 BY MR. TISI: 24 O Did the Personal Care Products Council 24 understanding this would not require a warning. 25 in any way analyze or -- or discuss the standard 25 BY MR. TISI: Page 413 Page 415 1 for providing when a label -- to add a warning on 1 Q Well, what was the standard? 2 a cosmetic product is required? 2 MR. LOCKE: Objection. 3 MR. LOCKE: Objection. 3 THE WITNESS: I'm not sure I understand THE WITNESS: We -- as I say, what we 4 4 that question. 5 did was we reviewed the science on ovarian cancer, 5 BY MR. TISI: 6 talcum powder, and our position is that there is 6 Q Okay. Did the standard require that --7 and if you don't know the answer, you don't know not evidence of a causative role, and therefore we 7 8 8 did not believe a -- a label is necessary. the answer, okay? 9 MR. TISI: Okay. Move to strike. 9 But does the standard for providing a 10 BY MR. TISI: 10 warning require that causation be proven, be unequivocal? 11 11 Q My question was a different one. 12 Does this opposition that was filed in 12 MR. LOCKE: Objection. That's beyond July of 2009 contain any discussion of what the 13 13 the scope. 14 standard is? 14 You can answer in your personal 15 MR. LOCKE: Objection. 15 THE WITNESS: No, it addresses the 16 16 THE WITNESS: I'm not sure what you mean by the standard for requiring a warning. 17 science. 17 BY MR. TISI: 18 BY MR. TISI: 18 Q Okay. Do you know whether or not the 19 Q Well, this is -- this is a response to a 19 20 standard requires that causation be proven before 20 request that a warning be added. 21 21 A Correct. Which FDA later said it a warning be added? 22 A I -- I think that sounds like a legal 22 doesn't require a warning. 23 question. I -- I --23 O That's not --24 Q I'm asking you since this was filed 24 MR. TISI: Move to strike. 25 on -- you're -- you're speaking here not as Linda 25 BY MR. TISI:

Page 416 Page 418 Q Okay. My -- my -- my question is, did 1 1 level of evidence that's required before a label 2 the PCPC consult what the legal -- what the legal 2 3 standard was for when a warning is required? 3 MR. LOCKE: Objection. Beyond the 4 MR. LOCKE: Objection. 4 scope. 5 5 THE WITNESS: I mean, I -- I -- I think BY MR. TISI: 6 it's fair to say we have a lot of lawyers at PCPC, 6 Q If you don't know, you don't know. 7 and if they felt this were inappropriate from a 7 A Yeah, I -- I guess I would say I don't 8 legal standpoint to have this position, we would 8 know, but I --9 not have that position. 9 Q That's fine. But you wrote this letter 10 10 anyway, you or Dr. Bailey wrote this letter to the BY MR. TISI: 11 Q Did they set out what the standard is in 11 FDA responding to requests for requiring a label. the letter? Is there anything in this letter --A Again, I would say certainly there was 12 12 13 first of all, who drafted this cover letter? 13 awareness within PCPC, and it was felt that this 14 14 A It was either myself or John Bailey. was appropriate as a response. Q Okay. Did you consult with -- either 15 Q Right. And there was -- but there was 15 16 one of you consult with what the standard is for 16 no discussion about what the standard is under the 17 when a warning is required before writing this 17 Code of Federal Regulations in this -- in this 18 letter? 18 letter, correct? 19 19 MR. LOCKE: Objection. MR. LOCKE: Objection. 20 THE WITNESS: I'm -- again, I'm not 20 THE WITNESS: And again, I would just 21 quite sure when what you mean "when a warning was 21 say our -- our view was that -- that there was not required." By whom? 22 22 a need for warning because of the lack of 23 BY MR. TISI: 23 evidence. 24 Q Well, you -- you know -- do you know 24 BY MR. TISI: 25 that warnings are added when a cosmetic product 25 Q Okay. Well, as -- as we discussed Page 419 Page 417 1 may cause -- there's evidence that they may cause 1 before, this issue was one that was debated in the 2 a potential harm? 2 medical and scientific community for almost 25 3 MR. LOCKE: Objection. Beyond the 3 years before this petition was filed, correct? 4 4 A It was a topic, yes. scope. 5 5 Q All right. And some epidemiologists You can answer in your personal 6 6 looking at the evidence felt that there -- there capacity. 7 THE WITNESS: I'm sorry. What's the 7 was sufficient evidence to raise a causal 8 8 question? inference, correct? 9 9 BY MR. TISI: MR. LOCKE: Objection. 10 Q Do you know that warnings can be added 10 BY MR. TISI: 11 voluntarily when there's evidence that the product 11 Q Including Dr. Epstein. 12 may cause a potential harm? 12 MR. LOCKE: Objection. MR. LOCKE: Same objection, and to form. THE WITNESS: Dr. Epstein did, but I 13 13 14 THE WITNESS: And as our position being 14 think the literature, as we point out and as we 15 that there was not support for that harm, we would 15 had our epidemiologists point out, that there is a 16 not have supported adding a voluntary label. 16 lot of inconsistency. 17 BY MR. TISI: 17 BY MR. TISI: Q I -- I understand. 18 Q Understood. My -- I understand that's 18 A We would not have said, yes, this should 19 19 your position. 20 20 My question, though, is a different one, be labeled. 21 21 Q But should -- do you not understand what Dr. Loretz. There were epidemiologists and -- and 22 22 scientists in the medical and scientific the standard is for a label? 23 MR. LOCKE: Objection. 23 communication who disagreed with the PCPC's view 24 24 of the sufficiency of the evidence. This was an BY MR. TISI: 25 Q What is -- what is the -- what is the 25 active debate, correct?

11 (Pages 416 to 419)

Page 422 Page 420 1 MR. LOCKE: Objection. 1 Citizen's Petition," and that would be July 2009. 2 THE WITNESS: That's probably fair to 2 Okav? 3 say, and certainly Dr. Epstein disagreed. 3 A Yes. 4 BY MR. TISI: 4 MR. LOCKE: I'm just going to object. I 5 5 mean it says "Comments" on it. It doesn't say O Right. And there were others. I mean 6 Dr. Cramer, another -- another doctor who you are 6 "opposition to," but --7 familiar with, wrote and published -- and 7 BY MR. TISI: 8 published in the literature several -- several of 8 Q But I think -- I think the testimony was 9 the studies. You know that he felt and published 9 this was in opposition to adding a warning, 10 that there was an inference of causation, true? 10 correct? 11 MR. LOCKE: Objection. 11 A Yes. We did not think a warning was THE WITNESS: I believe that would be 12 12 necessary. 13 true, and then the -- there were epidemiologists 13 Q Okay. So let's put that aside for a 14 who did not agree with that. 14 moment. 15 BY MR. TISI: 15 Oh, I'm sorry, before -- before we leave 16 Q Fine. Okay. And that kind of 16 this document, if you go to page 4 of 39 of this 17 illustrates a point that I think is important to 17 document, you attach a report. A Yes. 18 18 make here. 19 19 Looking at the evidence that -- some of Q PCPC attaches a report. And this is a report by a group called the Meta-Analysis 20 which was summarized in this letter, reasonable --20 21 scientists looking at the evidence could reach 21 Research Group. Correct? 22 different conclusions looking at that evidence, 22 A Yes. 23 and in fact, did reach different conclusions, Q Okay. And that's a group that you're 2.3 24 correct? 24 familiar with? 25 25 A Yes. MR. LOCKE: Objection. Page 421 Page 423 1 1 Q Okay. And it was prepared by a THE WITNESS: Yeah, there were different Dr. Michael Huncharek? 2 opinions. 2 3 BY MR. TISI: 3 A Yes. 4 4 Q Okay. And there were different opinions Q And a Dr. Joshua Muscat? 5 5 A Correct. based upon the evidence, correct? 6 A I don't want to go to what the -- what 6 Q And they both identify themselves as 7 the thoughts were, but I mean, there's a body of 7 being with the Meta-Analysis Research Group. 8 scientific literature, yes. 8 A As well as other affiliations, but yes. 9 Q Right. And that's not unusual. You've 9 Q All right. And we'll get into this in a 10 been in this business for -- for a while. 10 minute, but this report was initially written for 11 Scientists and doctors look at -- look at the 11 Johnson & Johnson, correct? 12 evidence, and some -- they can often disagree 12 A Yes. 13 about evidence, correct? 13 Q And it was then -- in fact, earlier 14 A That's true. 14 versions of this have "Prepared for Johnson & 15 Q All right. All right. So let's put 15 Johnson." This version that was submitted to the this opposition to the Citizen's Petition on our 16 16 FDA says "Prepared for the Personal Care Products Council." Correct? 17 timeline here, and this was --17 18 18 A That could be, yes. MR. TISI: Maybe we can switch back to 19 Q Okay. And it was actually prepared for this. 19 20 20 Johnson & Johnson, but --THE VIDEOGRAPHER: It is. It's in 21 21 A Originally. process. 22 MR. TISI: If I can see if I can write 22 Q Originally. It was not prepared for or initiated by the Personal Care Products Council, 23 23 it. 24 24 BY MR. TISI: correct? 25 Q This would be "PCPC opposition to 25 A We took it over, though, yes.

12 (Pages 420 to 423)

### Case 3:16-md-02738-MAS-RLS Document 9895-3 Filed 05/30/19 Page 78 of 565 PageID: 71322 Linda Loretz, Ph.D.

	Page 424		Page 426
1	Q Right.	1	conclusions at all. That's a
2	A I mean, and submitted it, yes.	2	Q Right. And in fact, these these
3	Q All right. But J&J did not submit the	3	doctors, Meta-Analysis Research Group, had been
4	report. The Personal Care Products Council did.	4	consultants to the talc industry before this,
5	A Correct.	5	correct?
6	Q Now, I think in your prior deposition	6	A They had
7	you said you had met Dr. Huncharek and Dr. Muscat	7	MR. LOCKE: Objection.
8	before, correct?	8	BY MR. TISI:
9	A I'm not sure if I ever met	9	Q I'm sorry. You may answer the question.
10	Dr. Huncharek. I know I met Dr. Muscat once upon	10	A They had, yes. Or Dr. Muscat had
11	a time.	11	reviewed for NTP.
12	Q Okay. Had you had occasion to	12	Q Okay. And you were aware through
13	communicate with them either on teleconferences or	13	Crowell & Moring that they were both retained to
14	by e-mail?	14	provide information on NTP for the 12 12th
15	A I had spoken to Dr. Huncharek.	15	review on carcinogens, correct?
16	Q Okay. How often?	16	MR. LOCKE: Objection.
17	A Once or twice.	17	THE WITNESS: I'm not sure if
18	Q Okay. Now, on page 6 of this document	18	BY MR. TISI:
19	is an introduction. Do you see that?	19	Q You ever heard of Crowell & Moring?
20	A Yes.	20	A I've heard of them, yes.
21	Q It identifies the second paragraph	21	Q Okay. Do you know did you
22	identifies this report as "an independent review	22	communicate with them through Crowell & Moring?
23	of the relevant data." Do you see that?	23	A Communicate with?
24	A Sorry, where?	24	Q Huncharek and Muscat.
25	Q Second second paragraph, second to	25	A Oh, no. No.
	Page 425		Page 427
1	last sentence.	1	Q Did you and you know that they
2	A Okay.	2	appeared as an industry representative for
3	Q It identifies this as "an independent	3	Dr. Muscat appeared at the IARC proceedings as an
4	review of the relevant data."	4	industry member?
5	A Okay.	5	A I do know that.
6	Q Do you see that?	6	MR. LOCKE: Well, wait wait one
7	A Yes.	7	second. When you say "they appeared," who are you
8	Q Okay. This was not an independent	8	referring to?
9	review of the relevant data, was it?	9	MR. TISI: I said Dr. Muscat.
10	MR. LOCKE: Objection.	10	
	Witt. Eocite. Objection.	1 - 0	MR. LOCKE: Okay.
11	THE WITNESS: I think it depends how you	11	MR. LOCKE: Okay. BY MR. TISI:
11 12			
	THE WITNESS: I think it depends how you	11	BY MR. TISI:
12	THE WITNESS: I think it depends how you define "independent." I mean these the	11 12	BY MR. TISI:  Q Are you aware of that?
12 13	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean,	11 12 13	BY MR. TISI:  Q Are you aware of that?  A I'm aware of that, yes.
12 13 14	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean, first of all, this was on behalf of our members,	11 12 13 14	BY MR. TISI:  Q Are you aware of that?  A I'm aware of that, yes.  Q You know who Robert Glenn is, don't you?
12 13 14 15	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean, first of all, this was on behalf of our members, not just J&J. They initiated the contact and got the report writing started.  I think independent in the sense that	11 12 13 14 15	BY MR. TISI:  Q Are you aware of that?  A I'm aware of that, yes.  Q You know who Robert Glenn is, don't you?  A I know who he is.
12 13 14 15 16	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean, first of all, this was on behalf of our members, not just J&J. They initiated the contact and got the report writing started.  I think independent in the sense that these were the conclusions of these	11 12 13 14 15 16	BY MR. TISI:  Q Are you aware of that? A I'm aware of that, yes. Q You know who Robert Glenn is, don't you? A I know who he is. Q Okay. You know he is with Crowell & Moring? A Yes.
12 13 14 15 16 17 18 19	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean, first of all, this was on behalf of our members, not just J&J. They initiated the contact and got the report writing started.  I think independent in the sense that these were the conclusions of these epidemiologists.	11 12 13 14 15 16 17 18	BY MR. TISI:  Q Are you aware of that? A I'm aware of that, yes. Q You know who Robert Glenn is, don't you? A I know who he is. Q Okay. You know he is with Crowell & Moring?
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12 13 14 15 16 17 18 19 20 21	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean, first of all, this was on behalf of our members, not just J&J. They initiated the contact and got the report writing started.  I think independent in the sense that these were the conclusions of these epidemiologists.  BY MR. TISI:  Q Right. But this report was written with	11 12 13 14 15 16 17 18 19 20 21	BY MR. TISI:  Q Are you aware of that? A I'm aware of that, yes. Q You know who Robert Glenn is, don't you? A I know who he is. Q Okay. You know he is with Crowell & Moring? A Yes. Q And you received e-mails from him, correct? A Well, not in relation to this.
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12 13 14 15 16 17 18 19 20 21	THE WITNESS: I think it depends how you define "independent." I mean these the epidemiologists that were retained I mean, first of all, this was on behalf of our members, not just J&J. They initiated the contact and got the report writing started.  I think independent in the sense that these were the conclusions of these epidemiologists.  BY MR. TISI:  Q Right. But this report was written with Johnson & Johnson and Imerys's input, correct?	11 12 13 14 15 16 17 18 19 20 21	BY MR. TISI:  Q Are you aware of that? A I'm aware of that, yes. Q You know who Robert Glenn is, don't you? A I know who he is. Q Okay. You know he is with Crowell & Moring? A Yes. Q And you received e-mails from him, correct? A Well, not in relation to this. Q Well, with relation to Huncharek and

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Page 428 Page 430 1 being copied was related to the IARC review. 1 what Dr. Huncharek did. 2 Q Okay. And you also understand -- we'll 2 Q Okay. Do you know whether or not they 3 3 were an organization that was a contract research talk about this in a moment -- they let you know 4 that there were publications that were being 4 organization? For example, do you know whether or 5 5 planned by Huncharek and Muscat, true? not they were litigation consultants? Do you know 6 MR. LOCKE: Objection. 6 whether or not they were -- you know, what they 7 7 THE WITNESS: I'm not sure. I may have were? 8 8 MR. LOCKE: Objection. known. THE WITNESS: I mean I think we were 9 BY MR. TISI: 9 10 10 Q Okay. We'll talk about those. We'll familiar with them from doing this. This to me --11 talk about those. 11 so we know they did this kind of meta-analysis, which again was something I know that both 12 But -- but the bigger picture, Doctor, 12 is that Huncharek and Muscat were people who had 13 13 Dr. Huncharek and Dr. Muscat did. So ... 14 MR. TISI: I'm going to -- I'm going to been in communication with the talc industry going 14 15 back to at least 2000 and perhaps before. 15 actually move to strike. 16 MR. LOCKE: Objection. 16 BY MR. TISI: 17 THE WITNESS: Muscat in 2000, I'm 17 Q My question was, do you know -- or did 18 18 you do any due diligence as to what Meta-Analysis certainly aware of that. 19 Research Group was? 19 BY MR. TISI: MR. LOCKE: Objection. 20 Q And you said you had spoken to Huncharek 20 21 21 THE WITNESS: No, because we knew who 22 22 A I spoke to him I believe around the time the authors were. (Exhibit No. 44 was marked for 23 23 of this, I think. I spoke to him once, I know 24 that, and I can't remember exactly when it was. 24 identification.) 25 Q Okay. Now, prior to the talc -- prior 25 BY MR. TISI: Page 429 Page 431 1 to this publication, had you ever heard of the 1 Q Okay. I'm going to show you Exhibit 2 Meta-Analysis Research Group ever? 2 No. 44. 3 MR. LOCKE: When you refer to "this 3 And I'm not concerned with the front 4 publication," you mean Exhibit 43? pages of it. But with an attachment. 4 5 MR. TISI: Correct. 5 Here you go. MR. TISI: I'm sorry? Oh, Tom, I'm 6 BY MR. TISI: б 7 Q Let me -- let me rephrase the question, 7 sorry, here you go. 8 8 MR. LOCKE: Thank you. because -- to be clear. 9 9 MR. TISI: Yep. Prior to these comments that were 10 submitted to the FDA in July of 2009 under the 10 BY MR. TISI: 11 letterhead of Meta-Analysis Research Group, had Q And if you go to the last -- and I'll 11 12 you ever had occasion to come across Meta-Analysis 12 just represent to you, this is a proposal from 13 Research Group before then? 13 Dr. Huncharek to Bob Glenn to do certain papers 14 A I honestly don't know. I believe 14 and research on behalf of Imerys in 2004. 15 Dr. Muscat's affiliation was not that in 2000. 15 But attached to it --16 Q It was American Health Foundation. 16 MR. LOCKE: Let's let the witness just 17 A That's what I remember as well. 17 read it first a second, just flip through the 18 Q Okay. So my question is, did you --18 pages. 19 prior to submitting this independent report on 19 MR. TISI: Oh, she can certainly do 20 behalf of the industry by a group called 20 that, Tom. 21 Meta-Analysis Research Group, did PCPC do any due 21 BY MR. TISI: 22 diligence as to who Meta-Analysis Research Group 22 Q And I'm going to ask you on the -- about 23 is and what their focus was? 23 the brochure that's attached on page 5. 24 A I -- I think the assumption was that 24 A (Peruses document.) 25 they were doing meta-analysis, which I know is 25 Q Since you took the time to read it, let

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Page 432 Page 434 1 1 me just ask you the question. Do you see that litigation? 2 this is a proposal to write two papers, one on 2 A I'm not sure. I knew that Dr. Muscat 3 meta-analysis on diaphragms and one a critical 3 was deposed, but I don't -- I don't think that's 4 review of the talc literature? 4 the same as what you're asking. 5 5 A Yes. Q And so my question to you is, did it 6 Q Okay. You know that they did publish 6 matter to you when you were submitting this on 7 two articles relating to that very specific --7 behalf of -- to the FDA as to whether or not these 8 those two specific topics, correct? 8 consultants who -- were basically people who would 9 A I believe so, yes. 9 be involved in litigation? 10 10 MR. LOCKE: Objection. Do you mean --Q Okay. And so this is a proposal by --11 by Dr. Huncharek to write such articles to 11 BY MR. TISI: Mr. Glenn, who I will represent to you was with Q Did you think about that? 12 12 13 the lawyers for Crowell & Moring for Imerys. 13 MR. LOCKE: Do you mean -- when you say 14 "this," you're referring to Exhibit 43, the A Okay. 14 15 Q Okay. Attached to that is a brochure 15 comments? 16 from the Meta-Analysis Research Group. Do you see 16 MR. TISI: Correct, in 2009. 17 that? 17 BY MR. TISI: 18 A I guess this is --18 Q Did you want to know -- did you even 19 MR. LOCKE: Page 5. 19 think to know whether or not these witnesses, 20 THE WITNESS: Okay. Okay. 20 Dr. Huncharek and Dr. Muscat, would be considered 21 21 or groomed for being experts in litigation? 22 Q Okay. This is a brochure. Did you 22 MR. LOCKE: Objection. 23 ever -- I think I -- I asked you before, but did 23 THE WITNESS: That's not --MR. LOCKE: Objection. Did you mean to 24 you ever ask -- first of all, the report that was 24 25 filed on behalf of the FDA, I believe your answers 25 say "these witnesses"? Page 433 Page 435 1 to interrogatories said it cost about \$50,000. 1 MR. TISI: These -- yes, these doctors. 2 A I think that's correct, yeah. 2 THE WITNESS: We hired them for their Q Okay. Did PCPC pay that or did J&J? 3 3 epidemiological expertise, and they're -- they 4 A I believe we did. 4 were not always favorable to us. I mean they 5 Q Okay. "We" meaning PCPC? 5 also -- Dr. Huncharek published on hair dyes, and 6 A I'm sorry. PCPC. 6 it was -- it was not favorable. So we -- we 7 Q On behalf of the talc industry? 7 consider them to be fair, and their scientist 8 A Yes. 8 arguments would stand. 9 Q And one of the things that the 9 BY MR. TISI: 10 Meta-Analysis Research Group identifies in the 10 Q Okay. Had you ever heard discussed --11 first paragraph that they do is they assist major 11 now I'm asking you as Linda Loretz -- had you ever 12 pharmaceutical companies and other clients in, 12 discussed that if this case went into litigation 13 quote, deciphering often complex, seemingly 13 that Drs. Huncharek and Muscat would be 14 contradictory, data using rigorous meta-analysis 14 consultants or experts? 15 methods. 15 MR. LOCKE: Objection. 16 Do you see that? 16 THE WITNESS: No. 17 17 BY MR. TISI: 18 Q Okay. Do you know that Meta-Analysis Q Do you see on the next page that it also 18 19 provides medical and legal consulting in Research Group went out of business shortly after 19 20 20 litigation? this --21 A That's what it says, yes. 21 A I don't know. I did not know that. 22 Q The expert witnesses. Do you see that? 22 Q Do you know that they became paid 23 23 litigation experts in 2010? A Yes. 24 Q Do you know that both Dr. Huncharek and 24 A No. 25 Dr. Muscat became expert witnesses in talc 25 Q Now, are you aware that in 2011, after

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Page 436 Page 438 1 the filing of this report to PCPC, that they took 1 talking about before. 2 their analysis that was paid for by PCPC and then 2 And it's on page 3 of the report, 3 made some modifications, but for the most part, 3 page 6 -- 6 of 9 of the letter. Do you see that? 4 published it as it was in the -- in the 4 5 5 literature? Q Okay. The Introduction says: "On б 6 May 13th, 2008, Samuel Epstein, MD, chairman of MR. LOCKE: Objection. 7 THE WITNESS: I'm -- I think I'm aware 7 the Cancer Prevention Coalition, submitted a 8 that there was a publication, but, no, I did not 8 Citizen's Petition to the Commissioner of the Food 9 9 know that was happening until after the fact -- we and Drug Administration seeking placement of a 10 did not know that that was happening until after 10 cancer warning label on talc products. The 11 the fact. 11 petition requests the Commissioner of the Food and Drug require that all talcum powders bear labels 12 (Exhibit No. 45 was marked for 12 13 identification.) 13 with warnings such as 'Frequent application of 14 talcum powder in the female genital area 14 BY MR. TISI: 15 Q I'm going to show you what I've had 15 substantially increases the risk of ovarian 16 marked as Exhibit No. 45. 16 cancer." 17 And this is a --17 Did I read that correctly? 18 (Phone interruption.) 18 A That's what it says. BY MR. TISI: 19 Q Okay. The second paragraph -- so that 19 just -- and that's true, that that's -- that 20 Q This is an article that I will represent 20 21 to you is very close to, if not identical in many 21 paragraph is true, that's what Epstein did. paragraphs, to the report that was filed on behalf 22 22 A I would say yes. of PCPC. Have you seen this before? Q Okay. Second paragraph is -- is your 2.3 23 24 A I've -- yes. 24 response or the summary of your response. 25 Q It was published in 2011. Correct? 25 "Given the multiple implications of such Page 437 Page 439 1 A Accepted April 2011, so -- yes. 1 warning labels, the Personal Care Products Council 2 Q Do you know -- do you know that there 2 sought an evaluation of the validity of the 3 was a -- actually a proposal to -- made to Imerys 3 scientific facts underlying this request. The that -- to turn this paper, "this" meaning the 4 Meta-Analysis Research Group was retained to 4 5 report that was submitted by PCPC in July of 2009, 5 provide an independent review of the relevant 6 into a publication? 6 data. Below are the findings of that review." 7 7 A No. We were not involved. Do you see that? 8 8 Q Okay. If you look at the back of the A Yes. 9 article, do you know -- does it acknowledge PCPC 9 Q I'm curious about the statement saying as having paid for this report? 10 10 "the multiple implications of such warning A No. labels." Do you see that? 11 11 12 Q Is there anything in that acknowledgment 12 A Yes. that would indicate that at the time that this 13 13 Q Can you tell us on behalf of the PCPC 14 article was published that they were paid 14 what the multiple implications of the warning litigation experts for the lawyers representing labels are that you were referring to? 15 15 Johnson & Johnson? MR. LOCKE: Objection. Obviously this 16 16 17 MR. LOCKE: Objection. 17 was written by doctors --THE WITNESS: No, not any 18 MR. TISI: I'm -- I'm -- I am --18 BY MR. TISI: 19 acknowledgments. 19 20 20 Q What are the multiple implications that BY MR. TISI: 21 21 were being considered there? Q So let's put this on our timeline here, 22 2011. And I'll put "H&M publication, 2011." 22 A Again, this -- this was written not by us. I mean, I think it's pretty obvious that that 23 Now, let's go back to the report that 23 was filed with the FDA. And I would like to go would have -- could have an impact -- I mean, 24 24 25 back to the Introduction section that we started 25 again, we didn't think a label was -- should be

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Page 440 Page 442 1 required because we -- because of the science 1 than stating what Dr. Epstein did, the first --2 behind it we believe was not supported, but 2 first sentence of that paragraph, you say that 3 3 obviously would have an impact on -- on the the -- that your consultants on your behalf say: 4 product if -- if it were. 4 "Given the multiple implications on such a warning 5 5 Q Okay. The "impact on the product," what label, the Personal Care Products Council sought б 6 an evaluation of the validity of the scientific do you mean? 7 A Well, we -- we -- I mean it --7 facts underlying this request." 8 8 So this statement is the predicate of Q Well, let me ask --9 A We don't think it should have a warning 9 why the PCPC got this report in the first place, 10 if it's -- if we don't believe that it --10 correct? 11 Q Let me ask you some -- I didn't mean to 11 A Sure. 12 interrupt you. Go finish, if you'd like. 12 Q Okay. And so the predicate was that 13 A No, just that if -- because we didn't --13 there were multiple implications of that warning, of a warning, should it be required. And this, to 14 we don't believe that the science shows causation, 14 we just did not believe you have a warning to be clear, is a request that warning labels be 15 15 16 scare people off of something if it's not real. 16 mandated. Correct? 17 Q Okay. So let me ask you -- I understand 17 A Correct. 18 your position that you did not think the evidence 18 Q And you were aware that companies can 19 supported a causal inference. 19 and in fact have voluntarily added a warning, 20 Putting that issue aside, the company 20 correct? 21 through its consultants assert -- make an 21 A Sure. 22 assertion that warnings labels would have 22 Q Okay. So this is different than that. 23 implications. Do you see that? 23 I mean companies can voluntarily add a warning. 24 A Yes. 24 25 Q And not only implications, have multiple 25 Q But this is in the absence of a company Page 441 Page 443 1 implications. Correct? 1 voluntarily adding a warning, they're going right 2 A That's what it says. 2 to the FDA and saying, The companies are not doing 3 Q Okay. And I'm curious as to what those 3 it, and we're going to ask you -- require you to 4 implications were from your perspective, from the 4 do it. Correct? 5 5 PCPC's perspective. A Yes. 6 Was there concern ever expressed that 6 Q All right. And the PCPC, as a predicate 7 adding a warning would have an impact on the 7 for opposing that requirement, laid out that there 8 members of the PCPC? You've heard that, correct? 8 are multiple implications to requiring that 9 9 warning. Correct? A Yeah, again --10 10 MR. LOCKE: Objection. Q Okay. 11 11 THE WITNESS: That's what it says, yes. A -- I think the reason that -- we would 12 not want that, though, is because we do believe 12 BY MR. TISI: the science doesn't support the need for a Q All right. And the multiple -- the 13 13 14 14 implications are -- I mean let's -- let's -- I'm warning. 15 Q I -- I understand. 15 going to lay out some for you and ask you whether they were things that were discussed at the time. 16 A It has to be part of the context of my 16 Was one of the implications that it 17 answer. 17 Q I'm going -- Doctor, I'm going to ask 18 would affect the commercial interests of the 18 you a lot about this document, okay? And we're 19 19 members of the PCPC? going to go through it probably more than you want 20 A With the context being that we did not 20 21 21 to. Okay? believe that it truly had this risk, you do not 22 A Sure. 22 want to affect sales and so forth without --23 O But before we do, I want to understand 23 O Okav. 24 24 A -- if it's -- if there's no reason for the context in which it's written. Okay? 25 And in the very first paragraph, other 25 having a warning.

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Page 444 Page 446 A Yes. 1 Q Understood. We're going to talk about 1 2 the reasons. 2 Q All right. And so what I'm trying to 3 3 explore with you is what potential -- and I'll put A Okay. 4 Q I just want to know the implications. 4 it right on the table -- what potential biases 5 5 might have been present when this opposition was 6 Q Right? 6 sent to the FDA. Okay? 7 A Yep. 7 A Okay. 8 8 Q So the first implication would be -- and Q All right. So we'll talk about the science and we'll talk -- but before we talk about 9 I will write it on here, "Implications of 9 10 the science, I want to talk about the prism 10 warnings. 1. Sales." 11 Had you ever heard in the context --11 through which you looked at the science. Okay? since there were multiple implications, had you 12 12 A Okay. 13 ever heard in the context that providing a warning 13 Q And one of the things that was a concern after this being in the medical literature for 25 to the members, we talked about sales. Had you 14 14 15 years would open up members to the potential -ever heard of any concerns about litigation? 15 16 for the reason why we're all here today, potential 16 A I can tell you that was not something we 17 lawsuits? 17 ever discussed. 18 18 Q Okay. Is it something you understood? A No. 19 19 Q You never heard that? A Sure. At some level, of course. Q Okay. And if sales -- people stop 20 MR. LOCKE: Objection. 20 21 THE WITNESS: We never talked about 21 selling talc, and use corn starch, for example, instead of talc, that may impact the membership of 22 22 that. the PCPC as well, correct? 2.3 BY MR. TISI: 23 24 O Never talked about that at all? 24 MR. LOCKE: Objection. 25 A No. 25 THE WITNESS: I mean I didn't -- no, Page 445 Page 447 1 Q You never heard that -- that adding a 1 that's not -- that's not what I thought. I mean 2 warning might -- might raise -- might cause people 2 to me that -- that wouldn't really make sense. I 3 to bring claims such as this? 3 mean if you have a product that's corn starch 4 4 instead of talc, it's still a product. So I don't A We just talked about the science. 5 5 Q I'm not -- I'm going to talk about the think that's really relevant. 6 science in a moment, okay? We're going to get to 6 BY MR. TISI: 7 7 Q Right. But Imerys -- Imerys doesn't the science. 8 8 manufacture corn starch, do they? But oftentimes -- you're aware as a 9 scientist that oftentimes the reason why we do 9 A No, but I -- I guess --10 10 Q So they would fall out of the -- they disclosures in medical and scientific literature 11 is so that people could understand the biases or might fall out of the PCPC, correct? 11 12 potential biases or potential conflicts of 12 A I don't -- no, I never thought about, 13 interest that the authors might have, correct? and I don't think -- I never ever heard anybody 13 14 MR. LOCKE: Objection. 14 mention that. THE WITNESS: Say it one more time. 15 15 Q Any of the -- any other -- since there were multiple implications, any other implications 16 BY MR. TISI: 16 you could think of as to why you sought to get 17 O Medical articles oftentimes come with 17 18 18 this independent evaluation to submit to the FDA disclosures about affiliations, conflicts of 19 19 in opposition to letting women know there was a interest. 20 20 potential for ovarian cancer based upon the A Sure. 21 21 Q And the reason why we do that -literature? 22 22 A Yes. A I think given --23 Q -- is so that people reading those 23 MR. LOCKE: Objection. articles can understand why -- perhaps biases that 24 24 THE WITNESS: -- given our position that the authors bring to the table, correct? 25 25 we don't believe there is a causal role, I don't

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Page 448 Page 450 1 think you want to put warnings on products 1 literature on ovarian cancer? 2 suggesting that there's some harm when there's 2 A No. 3 3 not, scaring people or having people think that Q Okay. Since 2009, did PCPC ever discuss 4 some harm that they've experienced has something 4 with its members whether or not its members should 5 5 to do with this when in fact it doesn't. voluntarily add an informational label or warning 6 6 label about perineal dusting with talcum powder BY MR. TISI: 7 Q So you were concerned about scaring 7 products? 8 8 people. With baby powder. A No. 9 A Yeah, a warning is --9 Q Do you know that some talcum powder 10 10 Q Okay. products have in fact voluntarily added warnings 11 A -- is a scary thing, sure. 11 or information about the potential risk of talcum Q And if -- if a woman was told that --12 12 powder products? 13 that talcum powder products, and we talked about 13 A I didn't know that, but --14 this for 25 years that was being discussed in the Q Are you familiar with a company called 14 15 medical literature, if they were concerned by 15 Belk -- Belcam Inc.? 16 that, there were other alternatives on -- on the 16 A No. 17 shelves, right? There was corn starch, correct? 17 Q Greenbriar? 18 MR. LOCKE: Objection. 18 A No. 19 THE WITNESS: Yeah, again, the context 19 O Assured? 20 to me is that if we did not believe that it was a 20 A No. 21 real risk, that's where you don't want to warn. 21 Q Okay. There are members -- there are 22 22 people who actually manufacture talcum powder BY MR. TISI: 23 23 Q And -- well, but that's my reason why I products that are not members of the PCPC, 24 asked you before what the standard was. If the 24 correct? 25 standard was -- is the standard for warning that 25 A I would assume so. Page 449 Page 451 1 you have to be convinced of a real risk? 1 Q Are you aware that some manufacturers 2 MR. LOCKE: Objection. 2 have stopped selling talcum powder products 3 BY MR. TISI: 3 altogether and use -- and just have decided to use corn starch, correct? Do you know that? 4 Q Or that there may be a risk. What is 4 the standard for a warning, and did you even know 5 5 MR. LOCKE: Objection. THE WITNESS: I guess I don't know that, 6 at the time you sent this to the FDA? 6 7 7 MR. LOCKE: Objection. but I could find it plausible. 8 THE WITNESS: Again, I would just say 8 BY MR. TISI: 9 there were people within -- within PCPC who know a 9 Q Okay. Let's get back to the response to 10 lot more on this topic than I do, and --10 the Citizen's Petition. 11 BY MR. TISI: 11 Do you know -- we mentioned before, and 12 Q Did they --12 I just want to make sure that we understand, this PCPC response was actually commissioned by 13 A -- the awareness of --13 14 Q Did you send this to the lawyers at the 14 Johnson & Johnson in 2008, correct? 15 PCPC, this letter? 15 A I believe they started the process 16 A This -- I can't recall exactly who read 16 rolling, yes. 17 it, but I can tell you that certainly, you know, 17 Q Well, it's more than starting the everything that -- when things like this happen, process. The report was actually written for J&J. 18 18 19 they are -- it's known without the associate --19 A I -- I -- yeah, I think when we got it, 20 throughout the association at the higher levels. 20 it was -- it was --21 Q Now, prior to this time, did the PCPC 21 Q It was pretty --22 ever discuss either with the FDA or whether or not 22 A The report had been -- was in pretty 23 it's members should voluntary add a warning or 23 good shape, yes. 24 24 Q It was -- it was pretty much written by precaution or informational statement about 25 cosmetic talc and the current state of the 25 the time you got it.

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Page 452 Page 454 submission, this was submitted by a PCPC employee 1 A I believe so, yes. 1 2 Q Did you understand this was a 2 by the name of John Bailey. I want to talk to you 3 collaborative response by J&J and Imerys 3 a little bit about who John Bailey is and was. 4 4 A Okay. primarily? 5 5 A I'm not sure that I did. Q Who is John Bailey? 6 6 A He -- at the time of this, he was the Q Did other manufacturers -- there are 7 other manufacturers of talcum powder products, 7 vice president of science -- the science 8 8 correct? department. He was my boss -- or, rather, the 9 A There are certainly other people on our 9 executive vice president of the science department 10 Talc Task Force or the people with an interest in 10 at PCPC. 11 talc. 11 Q Okay. He previously worked at the FDA, 12 Q Do you know --12 didn't he? 13 A Other companies, rather. 13 A He did. Q Do you know that -- whether they had 14 14 Q And in fact, he was hired directly from input into this PCPC response, or was it primarily 15 the FDA by PCPC. 15 16 a J&J, with the assistance of Imerys, production? 16 A That's correct. 17 A I believe we would have sent it to other 17 Q Okay. And at the time that he left the 18 people with interest. I mean, that's our normal 18 FDA in December of 2001, he was with what division, do you know? 19 process. 19 20 Q Do you know whether that was happening? 20 A Office of Cosmetics and Colors. 21 A I mean, I don't, but that would be our 21 Q And at that time in 2001, the NTP had 22 22 actually deferred consideration of talc as a -- a normal process. 23 23 (Exhibit No. 46 was marked for carcinogen, correct? A Yes. 24 identification.) 24 25 BY MR. TISI: 25 Q Okay. And when we say "deferred," I Page 453 Page 455 1 Q So I'm going to show you what I've had 1 want to stop and pause on that for a moment 2 marked as Exhibit No. 46. And it's a date -- and 2 because it -- I just want to make absolutely 3 you're not on this, but I'm doing this just to 3 clear, and we'll talk about this in a moment. 4 kind of see if I can hone in the time frame. 4 They deferred the question, they did not 5 This is an e-mail from Kathleen Wille. 5 decide the question. 6 Do vou know who Kathleen Wille is? б A That's what -- that was under the 7 A Yes. 7 official, what they did, yes. 8 8 Q Okay. She works with J&J? Q Okay. And so in that context, PCPC just 9 A Yeah, I'm not sure if she's still there, 9 immediately following that -- well, when it was 10 10 deferred, there was an understanding that the but yes. 11 Q And it's entitled "Response to Citizens issue might come up again. 11 12 Petition on Talc, Latest Review of the Data," and 12 A Yes. 13 its attachment is a J&J report. Do you see that? 13 Q And in fact, it did come up again, 14 14 correct? A Yes. 15 Q Okay. And it says: "This is the report 15 A Kind of. that we will -- that we will submit to FDA in 16 16 Q It came up with IARC? response to the Citizen's Petition. We originally 17 17 A Oh, it came up in other contexts, sure. 18 commissioned the work; however, the trade Q Came up in IARC? 18 19 association will be the submitter." 19 A Yes. 20 Q This issue -- and again, it bears Is that an accurate statement of what 20 21 happened? 21 repeating because I want to make sure -- at all 22 A I don't know, but I'm -- well, yes, they 22 times on this continuum, on this timeline, the 23 commissioned it, and we -- we submitted it, that's 23 issue of talcum powder products causing or 24 24 contributing to ovarian cancer was an active correct, yes. 25 Q Okay. Now, going back to the actual FDA 25 debate. Sometimes more active, sometimes less

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Page 456 Page 458 1 active. But this was something that was a concern 1 MR. LOCKE: Objection. 2 to your members throughout the entire time of this 2 THE WITNESS: Yes. 3 3 timeline. BY MR. TISI: 4 MR. LOCKE: Objection. Form. 4 Q And he was -- he was going to the very 5 5 THE WITNESS: It was being talked about same office that he ran, correct? 6 б by someone. A In -- at that meeting there was more 7 BY MR. TISI: 7 than just the Office of Cosmetics and Colors. 8 8 Q Right. And so in the context of hiring Q Well, we're going to talk about that. 9 Dr. Bailey, he was hired by -- by PCPC from the 9 But -- but the people who were -- the vast 10 10 division of the FDA, the Office of colors -majority of the people at that FDA employees were 11 Cosmetics and Colors --11 people from the Office of Cosmetics and Colors. 12 A Cosmetics and Colors. 12 A I'm not sure about the vast majority, 13 Q -- that would interact with the cosmetic 13 but certainly there were people there, and that --14 industry on talc issues, correct? that may well be right. 14 A As well as many other issues, yes. Q Including Dr. Katz. 15 15 16 Q Right. And the person who took over was 16 A Dr. Katz was there. 17 a Dr. Katz? 17 Q And I want to put this on a timeline in 18 18 a moment, but Dr. Bailey left PCPC after this A Yes. 19 Q And Dr. Katz worked for Dr. -- had 19 petition -- this opposition was -- was correct, filed? 20 worked for Dr. Bailey at the time, correct? 20 21 A I actually don't know that. 21 A He's -- he left, yes. I'm not sure 22 Q All right. And he was the director of 22 exactly -- the exact year, but yes. Q About 2011 -- 2010, 2011? 23 that office, correct? 23 24 A That's correct, yes. 24 A That sounds roughly right. 25 Q And when he left FDA in December of 25 Q Okay. So before we discuss the science Page 457 Page 459 1 that was provided by PCPC, and I told you we would 1 2001, he became -- he was hired in January of 2002 2 by PCPC. 2 do that, let's see if we can pause here and put 3 A I couldn't confirm those dates, but --3 together -- fill out our timeline a little bit 4 4 Q Okay. And he interacted with the -- and about the context of everything that happened. 5 5 we're going to talk about this -- he's writing the First of all, we talked about the fact 6 response to this petition that would go to the 6 that talcum powder products may cause or 7 very same division, the Office of Cosmetics and 7 contribute to ovarian cancer was a concern since 8 8 the early 1980s and it was debated throughout the Colors, that actually he ran while he was at the 9 FDA. 9 entire time, correct? 10 A Yes, although I think the heart of our 10 MR. LOCKE: Objection. 11 submission is the scientific analysis. 11 THE WITNESS: There were ongoing 12 Q Right. 12 happenings related to that topic, yes. A Not the cover letter, but the --13 13 BY MR. TISI: Q Okay. Can we say -- can we use the word 14 O But the cover letter -- the cover 14 15 letter -- well, let's -- let's call it what it is. 15 "consistent" here? It was a consistent topic of 16 He actually sent the letter and he actually met 16 discussion in the medical and scientific with you -- with you at the Office of Cosmetics 17 17 community? and Colors before this was filed in July. 18 18 A There were a number of publications, but 19 19 A Oh --I mean not every --20 20 Q I mean I'm not saying you woke up in the Q There was a meeting at the FDA --21 A Correct. 21 morning and discussed it. I'm saying that within 22 Q -- where you and Dr. Bailey went to the 22 this topic was a topic that was -- it wasn't just 23 FDA, previewed this document that Dr. Huncharek 23 a flash in the pan. It was something that was 24 24 discussed over the -- over this 25 years and Muscat had provided, and then filed it 25 subsequently, correct? 25 represented by this chart.

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Linda Loretz, Ph.D.

1 MR. LOCKE: Objection. 2 THE WITNESS: Again, with the 3 understanding that there were publications, but 4 not all of them showed any sort of association 5 BY MR. TISI: 6 Q And some did. 7 A and some did and some and some did 8 and some but there were a lot of weaknesses in 9 the  1 Q I'll show you a document could but that was an issue that in understood that the FDA was cor 4 A They 5 MR. LOCKE: Objection. 6 THE WITNESS: They have concern with, okay. 8 (Exhibit No. 47 was mark identification.)	PCPC knew and neerned about.
2 THE WITNESS: Again, with the 3 understanding that there were publications, but 4 not all of them showed any sort of association 5 BY MR. TISI: 6 Q And some did. 7 A and some did and some and some did 8 and some but there were a lot of weaknesses in  2 could, but that was an issue that in understood that the FDA was core. 4 A They 5 MR. LOCKE: Objection. 6 THE WITNESS: They have concern with, okay. 8 (Exhibit No. 47 was mark.)	PCPC knew and neerned about.
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TO THE TO THE TOTAL PROPERTY OF THE PROPERTY O	
Q Well, I mean, my question is that was an 10 BY MR. TISI:	
active debate, correct, what those studies meant?   11 Q I'm going to show you a	document that
12 MR. LOCKE: Objection. 12 I've marked as Exhibit No. 47, ar	
THE WITNESS: I guess that's fair to 13 minutes of the CTFA talc force.	
14 say. 14 And we're going to talk at	out this
15 BY MR. TISI: 15 later, but this is Exhibit No I s	
16 Q Okay. So can we write "Active debate 16 MR. LOCKE: Yes.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
17 between scientists." Is that okay? 17 BY MR. TISI:	
18 A Okay. 18 Q Now you see why I used	1994 is on my
19 MR. LOCKE: Objection. 19 A Mm-hmm.	
20 BY MR. TISI: 20 Q on my timeline here.	
21 Q Is that accurate? 21 A Yes, right, but the the	workshop.
22 MR. LOCKE: Same objection. 22 yes.	.,
23 THE WITNESS: I I suppose. 23 Q Okay. And this was a we	orkshop dated
24 BY MR. TISI: 24 April 12th, 1994, correct?	
25 Q Okay. All right. So, for example, some 25 A Yes.	
Page 461	Page 463
1 like Dr. Cramer or Dr. Epstein on one hand thought 1 Q Okay. It's actually writter	
2 there was that there was evidence of a causal 2 Stephen Gettings?	- <b>,</b>
3 association, and some people like Huncharek and 3 A Yes.	
4 Muscat thought there was not. 4 Q Who is Dr. Gettings?	
5 MR. LOCKE: Objection. 5 A Dr. Gettings was my pred	ecessor.
6 THE WITNESS: There were different 6 Q All right. And this is a re	
7 opinions, yes. 7 meeting amongst this is the Tale	_
8 BY MR. TISI: 8 Party Task Force. Among other the	
9 Q Based on the same literature. 9 Johnson and the predecessor for I	-
10 A Yes. 10 there.	
11 Q Okay. Now, another point before we put 11 A Yes.	
12 things on a timeline, the PCPC knew that the FDA   12 Q Okay. And I'm going to c	come back to
had been concerned about the issue since at least 13 this in a minute when I talk about	
the 1990s, correct? 14 which we talked about, which is s	
15 MR. LOCKE: Objection. 15 A Okay.	
THE WITNESS: They responded before, 16 Q But but I'm just concern	ned with point
17 yes. 17 number 1. It says: "It was noted to	_
18 BY MR. TISI: 18 still appears to be concerned with	
19 Q But they were concerned about the issue. 19 ovarian cancer as evidenced by th	
20 MR. LOCKE: Objection. 20 the NTP."	
21 THE WITNESS: I I guess, yes. I 21 Do you see that?	
22 mean 22 A Yes.	
1 = 11 100.	in data
	is date,

22 (Pages 460 to 463)

Page 464 Page 466 was talking before, people can look at the same 1 A Okay. 1 2 Q Is that accurate? 2 evidence and come to different conclusions, 3 A I'm going to say yes. 3 correct? 4 Q Okay. So let's put this on our timeline 4 A I think there was some different 5 here, 1994. And this would be "Task force with 5 evidence. I think it really was bringing forth б the FDA, concern about ovarian cancer." б some things that were mistaken in the draft 7 By the way, ovarian cancer, this is not 7 report, particularly regarding mineralogy and --8 8 a trivial issue, is it? and so forth. 9 A No. 9 Q Right. And one of the things -- one of the things that was the basis of the deference is 10 O And ovarian cancer is a -- ovarian 10 11 cancer is -- affects 20 -- 20,000 -- 20,000 women 11 that there was not a clear understanding of what a year get diagnosed with ovarian cancer, correct? at that time was in talcum powder products. 12 12 13 A Yes. 13 MR. LOCKE: Objection. THE WITNESS: I think there wasn't 14 Q It has a high mortality rate. Correct? 14 A Yes. Yes. 15 also -- there was not a clear definition of -- in 15 Q Very serious. 16 fact, when they wanted to look at it again or 16 17 A Absolutely. 17 considered looking at it again, they changed the Q And by contrast, baby powder is not a 18 18 name of what they were going to look at, because necessary pharmaceutical, correct? 19 it was hard -- it was not clear what they were 19 trying to look at, and that was something that got 20 MR. LOCKE: Objection. 20 21 BY MR. TISI: 21 discussion at the NTP, and I think that made a 22 22 Q Is it fair to say you can live without difference and explains part of why there were baby powder? different conclusions from the first two review 23 23 24 MR. LOCKE: Objection. Beyond the 24 groups. 25 25 BY MR. TISI: scope. Page 467 Page 465 1 BY MR. TISI: 1 Q All right. And the third review group 2 Q Talcum powder. 2 was not unanimous, was it? 3 A Yes. 3 A They -- they did do a vote. I -- I've 4 been calling it seven to three against listing, 4 O Now, in 2000, we have the NTP 10th 5 5 and then they -- and then they decided to defer Report on Carcinogen, and we talk about the word 6 "defer." 6 because there were --7 7 And I want to write that clearly because Q And again, that's -- that's -- that's the kind of example that I'm talking about of even 8 my handwriting is terrible. 8 9 Okay. And they deferred the question. 9 if it was seven to three against listing talc, 10 A They did. They did vote. They voted, 10 there were three people who thought that it should but then they deferred. 11 11 be listed, correct? 12 Q Right. 12 A Sure. 13 A But they voted against listing seven to 13 Q So this is -- this is kind of 14 three, but then they deferred. 14 crystalizing what we've been talking about, which Q Well, there were different -- okay. is different scientists can look at the evidence 15 15 Since you raised that, let's -- you knew this was and reach different conclusions, true? 16 16 going to happen. I was not going to get into it, A Yes. 17 17 18 but let's -- let's -- there were three committees 18 Q And in fact, did reach different 19 that looked at the -- looked at this, correct? 19 conclusions, correct? 20 20 A Mm-hmm. A Yes. 21 21 Q Two of them voted in favor of listing. Q All right. Okay. So we put that on our 22 22 timeline here. A That's correct. 23 Q And one voted against, correct? 23 Now, prior to that last discussion --24 24 prior to that deferral, that last meeting, the Α Yes. 25 Q Okay. And that's kind of the issue I 25 PCPC actually drafted or commissioned a report,

23 (Pages 464 to 467)

Page 468 Page 470 1 correct? 1 that at the actual meeting, but I -- that's what I 2 A You mean -- to be submitted to the 2 recall. I think we walked away knowing where they 3 NTP --3 came out, but I -- I could be wrong on that, but, 4 4 yes, it was confirmed then. Certainly. Q Yes. 5 5 A -- for the meeting? Yes. (Exhibit No. 49 was marked for 6 Q Yeah. And I'm just going to identify б identification.) 7 it because I don't want to go into it, but -- but 7 BY MR. TISI: 8 here is a copy of the actual letter, Exhibit 8 Q Okay. And I'm going to hand you Exhibit 9 No. 48. 9 No. 40 -- 49. And this is the Code of Federal Regulations dated 2005. But if you look at the 10 (Exhibit No. 48 was marked for 10 11 identification.) 11 back, the last page with a 12 Bates stamp at the 12 12 BY MR. TISI: end. 13 Q And one of the things that the -- and 13 A Okay. 14 this would have been -- we'll put it on our Q And it says the basis was the NTP 14 timeline, this would have been December of 2000 15 deferred -- do you see that "Basis for 15 16 and -- 2000. So we will put "PCPC CFTA 16 nomination"? 17 17 submission." A Yes. 18 And the only reason I bring this up is 18 Q It says: "The NTP deferred 19 Dr. Muscat is the very same doctor who -consideration of listing talc asbestiform and 19 20 Dr. Muscat wrote a report that was submitted to 20 non-asbestiform talc in the 10th RoC because its 21 NTP, correct? 21 2000 review of talc found that there's been 22 22 considerable confusion over the mineral nature and A That's correct. 23 23 Q All right. And it's the very same consequences of talc, both containing asbestiform 24 Dr. Muscat that wrote the report with -- which was 24 fibers and not containing asbestiform fibers." 25 a Citizen's Petition with Dr. Huncharek. 25 Do you see that? Page 469 Page 471 1 1 A It is. A Yes. 2 Q Okay. So we're going to put "Muscat" 2 Q It further says: "It became evident 3 3 that the literature on both forms of talc with few 4 Now, Dr. Muscat was actually recommended 4 exceptions provide inadequate characterization of 5 to the PCPC by Johnson & Johnson, correct? Back 5 the adequate material under study," and you see --6 in 2000. 6 and it just continues from there. 7 7 A I think that's correct. Do you see that? 8 A Yes. 8 Q So I don't have to use a document. Is that correct? I'm happy to use the document, 9 9 Q Okay. And so the question at that point 10 but -was deferred because there was a question as to 10 A Okay. Then I'm going to say I think --11 11 what was cosmetic talc. 12 yes, I believe that's correct. 12 A Well. I mean this is where it was Q Okay. We just cut ourselves five 13 13 withdrawn. 14 minutes, so --14 Q No, withdrawn --15 A Yea. 15 A This is 2005. 16 Q All right. And just to kind of put it 16 Q 2005. But in the basis for -- it talks 17 again on our timeline, when did the -- when did 17 about what happened in the -the NTP defer the issue of whether or not talc was A Oh, the deferral that they're referring 18 18 19 a carcinogen? 19 to, yes, correct. 20 Q Okay. All right. And then in 12, in A I believe they actually did it at their 20 21 actual meeting, which was in December of 2000. 21 the -- it was renominated in 2004, correct? 22 Q 2000. And -- you became aware of the 22 A Right. 23 actual deferral in the CFR? The Code of Federal 23 Q Right. And so I'm going to put year 24 Regulations actually lists it as being --24 "2004," I'm going to put "renominated NTP." NTP. 25 A Yeah, I mean I -- I thought they said 25 My handwriting is terrible.

24 (Pages 468 to 471)

	Page 472		Page 474
1	And but at that time it the IARC	1	possible, correct? To be.
2	had also taken up the issue, correct?	2	A Yes.
3	A I'm not sure when I learned about IARC	3	Q Now, in 2005, you know that Dr. Muscat
4	taking up the issue, but I think they I mean,	4	and Huncharek were retained by Imerys and a law
5	so I'm not sure.	5	firm to write a meta-analysis and a review paper
6	Q Okay. And IARC is what?	6	on tale, correct?
7	A International Agency for Research on	7	MR. LOCKE: Objection.
8	Cancer.	8	THE WITNESS: I don't think I knew that,
9	Q Is it a reputable organization?	9	no.
10	A It's an arm of the World Health	10	MR. TISI: Okay. Let me show you what I
11	Organization.	11	would like to have marked as Exhibit No. 50.
12	Q Is it one that in your view is one that	12	(Exhibit No. 50 was marked for
13	is does good science?	13	identification.)
14	A They have I mean, it's	14	BY MR. TISI:
15	Q You may disagree with them on occasion,	15	Q And I'm not concerned with the top
16	but do they do good science?	16	e-mail because that's not to you, but the bottom
17	A It's a closed process, and I think	17	e-mail is to you, correct?
18	they're considered reputable. It is a very closed	18	A Yes.
19	process.	19	Q Okay. It's from Robert Glenn?
20	Q When you say "closed," they don't have	20	MR. LOCKE: Let's let
21	people from industry who come in and and	21	MR. TISI: I'm going to. I'm just going
22	participate, correct?	22	to
23	A Well	23	MR. LOCKE: the witness just read it.
24	Q People affiliated with industry cannot	24	MR. TISI: I'm going to have to I'm
25	sit on the panels, correct? There are limitations	25	just going to direct her to what it is before we
23	sit on the paners, correct: There are minitations	23	just going to direct her to what it is before we
	5 450		- 485
1	Page 473	1	Page 475
1	into who can sit, correct?	1	do it, because if she didn't get it, then I'm not
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	into who can sit, correct?  MR. LOCKE: Objection.  THE WITNESS: That is true, but it's also closed in the sense basically they decide on a working group and that's the working group. So are those the best people always? I mean, I think there's that there's that question of you know, it's like any process, it's BY MR. TISI:  Q Have you ever seen an unqualified person on an IARC panel?  A I I mean, I really can't answer that. You know.  Q Okay. All right. So IARC review was in 2006, correct?  A Yes.  Q Okay. And they considered the issue, and they found that cosmetic talc would be a possible carcinogen. They looked at the evidence, right?  MR. LOCKE: Objection.  THE WITNESS: They said limited	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	do it, because if she didn't get it, then I'm not going to go there. BY MR. TISI: Q This is an e-mail to you from Robert Glenn. A Okay. Q Do you see that? A Yes. Q And it's dated August 3rd, 19 2005. A Okay. Q Okay. And it's entitled "Rothman Proposal for Updating CTFA Submission on Comments to NTP." Correct? A I'm sorry, where are you? Q It's the subject matter. A Yes. Q Okay. And it's by Crowell & Moring LLP. That's the law firm. A Okay. Q Do you see that? A Yes. Q So why don't you follow Mr. Locke's

25 (Pages 472 to 475)

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Linda Loretz, Ph.D.

	Page 476		Page 478
1	MR. TISI: Actually, would this be a	1	cancer."
2	good time for a break?	2	Do you see that?
3	MS. FRAZIER: Yes.	3	A Yes.
4	MR. TISI: For you, I will do almost	4	Q Okay. So it's talking about two
5	anything.	5	different papers, right?
6	THE VIDEOGRAPHER: All right. Off the	6	A Yes.
7	record, Counsel?	7	Q Okay. So does this refresh your
8	MS. FRAZIER: Thank you.	8	recollection as to whether or not you were aware
9	THE VIDEOGRAPHER: The time is 10:43	9	in the 2000s that Huncharek and Muscat were
10	a.m. We're going off the record.	10	actually consultants for the law firm representing
11	(Recess.)	11	Imerys, which is is Luzenac.
12	THE VIDEOGRAPHER: The time is 10:58	12	A I would say this would refresh my
13	a.m., and we are back on the record.	13	memory, yes.
14	BY MR. TISI:	14	Q Okay. So we have on our chart here in
15	Q Dr. Loretz, have you had an opportunity	15	2005 2006 is IARC review, 2005 and I'm going
16	to look at Exhibit No. 50, the e-mail from	16	to try to write real because on a break folks
17	Mr. Glenn at Crowell & Moring?	17	told me my handwriting was abysmal. So we have
18	A Yes.	18	"Huncharek, Muscat, two papers." One a review
19	Q And Mr. Glenn worked for Crowell &	19	and, two, diaphragm.
20	Moring, but you know that he's a toxicologist,	20	Is that correct? That's what that
21	correct?	21	document says?
22	A I probably knew that at the time.	22	A What year are you putting that
23	Q Okay. And do you know that he was	23	Q 2005.
24	also previous to working for the law firm	24	A Or it looks those yeah, I don't know
25	representing Imerys, do you know that he was also	25	when the publication date, though.
	Page 477		Page 479
1	a prior president of the Industrial Minerals	1	O Right. The publications, actually you
1 2	a prior president of the Industrial Minerals Association of North America?	1 2	Q Right. The publications, actually you know that they they actually published two
	• •	1 2 3	know that they they actually published two
2	Association of North America?  A I don't that doesn't sound familiar.	2	know that they they actually published two articles bearing on the very same topic
2	Association of North America?  A I don't that doesn't sound familiar.	2 3 4	know that they they actually published two articles bearing on the very same topic subsequently.
2 3 4	Association of North America?  A I don't that doesn't sound familiar.  Q Okay. So it talks to Mark Ellis at IMA	2 3	know that they they actually published two articles bearing on the very same topic subsequently.  A Yes, exactly.
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2 3 4 5 6 7	Association of North America?  A I don't that doesn't sound familiar.  Q Okay. So it talks to Mark Ellis at IMA  North America and to yourself.  And I'm interested in the first	2 3 4 5 6 7	know that they they actually published two articles bearing on the very same topic subsequently.  A Yes, exactly.  Q Okay. And I'm going to identify them
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Association of North America?  A I don't that doesn't sound familiar.  Q Okay. So it talks to Mark Ellis at IMA  North America and to yourself.  And I'm interested in the first paragraph. The first paragraph says: "As you may know, we represent Luzenac America in assisting them in preparation of comments to the NTP and IARC regarding carcinogen classification of talc. They have sponsored projects with Drs. Huncharek and Muscat related to reviewing the literature on talc and ovarian cancer, and conducting a meta-analysis of talc and ovarian cancer."  Do you see that?  A Yes.  Q Okay. So two different things, reviewing the literature on talc and conducting a meta-analysis.  Do you see that?  A Yes.  Q Okay. It says: "Both are nearing	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	know that they they actually published two articles bearing on the very same topic subsequently.  A Yes, exactly. Q Okay. And I'm going to identify them again to put on our timeline. A Okay. (Exhibit No. 51 was marked for identification.) BY MR. TISI: Q I'm going to attach Exhibit No. 51, which is a meta-analysis on diaphragms. Is that and that's dated 2006. I'm sorry, it's dated 2007. Correct? A Correct. Q And I'm going to start using below the line, so it's 2007. And diaphragm publication, I'll write "Huncharek and Muscat." And what exhibit is that? I wrote that A 51.

26 (Pages 476 to 479)

	Page 480		Page 482
1	Q Okay. And then we have Exhibit No. 52	1	THE WITNESS: And I guess I would again
2	is a critical review article that they wrote.	2	say that independent in the sense that these are
3	And you're familiar with that article,	3	their conclusions, but and submitted on behalf
4	right?	4	of us, which was clear.
5	A Yes.	5	BY MR. TISI:
6	Q And when I say you reviewed, you you	6	Q Right.
7	were familiar with it, you were familiar with it	7	A On behalf of industry.
8	at the time, right?	8	Q But they had been long-time consultants
9	A At the time of its	9	for the industry. Correct?
10	Q Publication.	10	A They had been consulting before then,
11	A I assume	11	yes.
12	Q Or shortly thereafter.	12	Q Okay. For at least 15 on talc for at
13	A Yeah, I assume so, yes.	13	least 15, 18 years, correct?
14	Q So 2008, this is the critical review,	14	MR. LOCKE: Objection.
15	tale and ovarian cancer. And this is 2008. And	15	THE WITNESS: Where did you come up with
16	this is Exhibit 52. And that's Huncharek and	16	that? 2000
17	Muscat.	17	BY MR. TISI:
18	Okay. And so far we have Dr. Muscat	18	Q 2000 to 2008 I'm sorry. 2000
19	appearing in 2000. Correct?	19	A 2009.
20	A Yes.	20	Q Okay. Let's say nine years, you're
21	Q We have him working on papers in 2005	21	right. You're right.
22	for the lawyers representing Imerys, correct?	22	All right. So now let's move forward.
23	A Yes.	23	We talked about IARC.
24	Q Which you were aware of.	24	So now, I want to again fill out the
25	2007, they write a publication. And	25	timeline so the jury understands what's going on.
		l .	
	Page 481		Page 483
1	Page 481 then in 2008, they write a publication. And	1	Page 483 2008, Dr. Epstein for the Cancer
1 2		1 2	
	then in 2008, they write a publication. And		2008, Dr. Epstein for the Cancer
2	then in 2008, they write a publication. And 2009 '8 and '9, they're filing the petition	2	2008, Dr. Epstein for the Cancer Prevention Coalition files asks that warnings
2	then in 2008, they write a publication. And 2009 '8 and '9, they're filing the petition they're drafting the response to the petition as	2 3	2008, Dr. Epstein for the Cancer Prevention Coalition files asks that warnings be mandated, correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	then in 2008, they write a publication. And 2009 '8 and '9, they're filing the petition they're drafting the response to the petition as a, quote, independent review. Right?  A Yes.  Q But the truth of the matter is, as we showed on our timeline, is they had been a consistent consultant not only for PCPC but for other members of the PCPC throughout the 2000s, correct?  MR. LOCKE: Objection.  THE WITNESS: I mean, they're they're filing the filing that we did came through us. That was very clear.  BY MR. TISI:  Q Okay. That's a different question.  Okay. You identified this as an independent review, right?  A That yes.  Q Okay. But when I asked you before are you sure they're independent, these these two scientists had been paid consultants for not only	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	2008, Dr. Epstein for the Cancer Prevention Coalition files asks that warnings be mandated, correct?  A Correct.  Q Your organization files an opposition to that in July of 2009, correct?  MR. LOCKE: Objection.  THE WITNESS: Right. We filed saying we didn't think those warnings should be mandated. BY MR. TISI:  Q With the FDA.  A Correct.  Q Filed signed by Dr. Bailey, who used to work at the FDA in the very division that would be considering the petition, correct?  A That's correct.  Q Okay. And do you know whether or not any other organizations were even aware of this petition to weigh in on it? In other words, are you aware of anybody else who filed a response to the FDA I mean to the Citizen's Petition?  A I may have known at the time, but I

27 (Pages 480 to 483)

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Page 484
                                                                                                        Page 486
 1
       BY MR. TISI:
                                                             1
                                                                      A That's true.
 2
           Q All right. I went to the FDA website
                                                             2
                                                                         MR. LOCKE: Objection. Beyond the
                                                             3
 3
       and pulled a copy -- Exhibit 53, I pulled a copy
                                                                   scope.
 4
       of it, and as I read it, the only comment that was
                                                             4
                                                                   BY MR. TISI:
 5
                                                             5
       actually provided was by the PCPC.
                                                                      Q That's true, correct?
 6
              Does that refresh your recollection?
                                                             6
                                                                      A Yes.
 7
           A As I say, I can't remember, but I have
                                                             7
                                                                         MR. LOCKE: Objection.
 8
                                                             8
       no reason not to think that's true.
                                                                   BY MR. TISI:
 9
           Q Okay. And just to kind of fill out a
                                                             9
                                                                      Q And just for clarity of the record, the
                                                                   denial letter from the FDA dated April 2014 -- I'm
10
       timeline because I want to make it clear that I
                                                            10
11
       don't want to hide anything from the jury here, in
                                                            11
                                                                   sorry, it's dated 2014.
12
       2015, the petition was denied.
                                                            12
                                                                      A Yeah, it's '14. I wasn't sure about
13
           A That's correct.
                                                            13
                                                                   that.
                                                           14
14
           Q So write "2005, FDA," and --
                                                                      Q I stated 2015. You know, you're
15
              MR. TISI: Do you have a copy of the
                                                            15
                                                                   correct. You're correct. It's Exhibit No. 54.
16
       denial? I'll attach that in a moment.
                                                            16
                                                                         (Exhibit No. 54 was marked for
17
       BY MR. TISI:
                                                            17
                                                                         identification.)
18
           Q And so from the outside, what the FDA
                                                            18
                                                                   BY MR. TISI:
                                                            19
19
       had before it was the Epstein petition and the
                                                                      O Now, I want to talk about -- now that we
20
       PCPC response. Is that -- and then some four
                                                            20
                                                                   have our timeline out of the way, I want to talk
21
       years later or five years later, it denied the
                                                            21
                                                                   about the Citizen's Petition and the arguments you
                                                            22
22
                                                                   made in them and the circumstances surrounding its
       petition.
                                                            23
2.3
              MR. LOCKE: Objection.
                                                                   actual filing. Okay?
24
              THE WITNESS: Okay.
                                                            24
                                                                      A Yes.
25
       BY MR. TISI:
                                                            25
                                                                      Q Now, prior to the actual filing of
                                             Page 485
                                                                                                        Page 487
 1
                                                             1
                                                                   the -- the opposition to this Citizen's Petition,
           Q Is that -- is that correct?
 2
              MR. LOCKE: Objection.
                                                             2
                                                                   we'll just -- can I just call it "the opposition,"
 3
              THE WITNESS: As far as I know, yes. As
                                                             3
                                                                   and we know we're talking about something
 4
       I say --
                                                             4
                                                                   containing the opposition to the Citizen's
 5
                                                             5
                                                                   Petition?
       BY MR. TISI:
 6
           Q All right. Is there anything -- do you
                                                             6
                                                                      A Yes.
 7
       know why it took the FDA five years or six years
                                                             7
                                                                      Q Prior to filing the PCPC's opposition in
 8
       to actually act on this petition?
                                                             8
                                                                   July, and we looked at this earlier, you and --
 9
           A I don't. I know that it typically takes
                                                             9
                                                                   when I say "you," I mean you personally -- you and
10
       them years to respond to petitions, but I couldn't
                                                            10
                                                                   your colleagues at the PCPC and the companies
11
       say anything specific about this one.
                                                            11
                                                                   represented by the lawyers on this table went and
12
           Q Well, petitions related to cosmetics, on
                                                            12
                                                                   met with the FDA about the Citizen's Petition,
13
       the scheme of things -- I mean you work with the
                                                            13
                                                                  correct?
14
       FDA, you know the FDA does a lot of different
                                                            14
                                                                         MR. LOCKE: When?
15
       things. It deals with pharmaceutical drugs, it
                                                            15
                                                                         THE WITNESS: One other company as well.
16
       deals with over-the-counter drugs, it deals with
                                                            16
                                                                   BY MR. TISI:
                                                                      Q Unilever.
17
       the blood supply, it deals with a lot of different
                                                            17
18
                                                                      A Unilever.
       things, correct?
                                                            18
19
           A Not the Office of Cosmetics and Colors,
                                                            19
                                                                      Q Okay. But certainly Johnson & Johnson
20
                                                            20
                                                                   is by far the biggest contributor to -- in terms
       but other parts of the FDA, sure.
21
                                                            21
           Q Right. But the -- but the FDA as a --
                                                                   of resources to the Talc Task Force, correct, in
22
       as a whole -- I mean would it be fair to say that
                                                            22
                                                                   terms of money?
                                                                         MS. FRAZIER: Objection.
23
       on a scale of things, cosmetics are not as heavily
                                                            23
24
                                                            24
                                                                         MR. LOCKE: Objection.
       regulated or looked at as is, for example,
25
       pharmaceutical drugs or over-the-counter drugs?
                                                            25
                                                                         THE WITNESS: I think what I've seen,
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28 (Pages 484 to 487)

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	Page 488	Page 490
1	they're the biggest contributor.	1 THE WITNESS: That sounds roughly right
2	BY MR. TISI:	2 from the numbers I've seen.
3	Q I mean by a factor of a lot, correct?	3 BY MR. TISI:
4	MS. FRAZIER: Object to form.	Q Okay. And so the PCPC and Johnson &
5	BY MR. TISI:	Johnson and Imerys and Unilever went to go meet
6	Q I mean, it's a big they're the	6 with the FDA about the Citizen's Petition,
7	they're the major funder of the Talc Task Force,	7 correct?
8	correct?	8 A Yeah, I'm not sure if it was set up
9	MS. FRAZIER: Object to form.	9 specifically about the Citizen's Petition, but I
10	THE WITNESS: But they're not the only	know that certainly got discussed. So yes.
11	funder.	11 Q Well, we'll talk we're going to talk
12	BY MR. TISI:	about have you reviewed those those memos
13		
14	Q And in the top two or three is Imerys as	before today?  A I think I I reviewed the memo. I'm
15	well, correct?  A That's correct.	
16		S
	Q Okay. So while there may be many other members of the that have an interest in	
17		Q Okay. Well, did you
18	talc, the two big gorillas in the room are J&J,	A I don't disagree with that.
19	the manufacturer of talcum powder products like	Q But did you try to investigate that?
20	Johnson & Johnson's baby powder and Shower to	Because that's an important point. How did that
21	Shower, and the mining company who provides that	meeting get set up?
22	talc for use in the product, correct?	A I know Dr. Bailey set it up.
23	MR. LOCKE: Objection.	Q Dr. Bailey, the guy who used to work at
24	MS. FRAZIER: Objection to form.	the division
25	THE WITNESS: I mean we have	25 A Correct.
	D 400	
	Page 489	Page 491
1	THE REPORTER: Counsel, we can't hear	1 Q called the division he used to work
1 2		Q called the division he used to work for to see if he could set up a meeting?
	THE REPORTER: Counsel, we can't hear	Q called the division he used to work for to see if he could set up a meeting? A Yes.
2	THE REPORTER: Counsel, we can't hear you down here.	<ol> <li>Q called the division he used to work</li> <li>for to see if he could set up a meeting?</li> <li>A Yes.</li> <li>Q And that meeting occurred in May of</li> </ol>
2	THE REPORTER: Counsel, we can't hear you down here.  MS. FRAZIER: No, it's okay. I was	Q called the division he used to work for to see if he could set up a meeting? A Yes.
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29 (Pages 488 to 491)

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	Page 492		Page 494
1	identification.)	1	predominant number of people at this at this
2	BY MR. TISI:	2	meeting were from the office that Dr. Bailey ran,
3	Q And just I can correct the error so we	3	the Office of Cosmetics and Colors, I was correct?
4	can correct it going forward. It's from John	4	A I would say you were correct, yes.
5	Bailey from Personal Care Council dated Monday,	5	Q Thank you. I like being correct.
6	May 11th, 2009.	6	And you attended that meeting?
7	Do you see that?	7	A I did.
8	A I'm sorry. The oh, yes.	8	Q Okay. Have you seen the final now,
9	Q The e-mail.	9	this is a fairly lengthy, several single-spaced
10	A Right, the e-mail.	10	pages of notes about what happened at that
11	Q It's to, among other things, you?	11	meeting?
12	A Yes.	12	A Okay. Yes.
13	Q Okay. And it's a meeting notes from	13	Q Do you see that?
14	the meeting of the FDA on talc.	14	A Yes.
15	A Yes.	15	Q Okay. Have you seen the FDA version
16	Q Okay. And it says: "All: Below are my	16	of of that?
17	attached notes from the FDA meeting on Friday."	17	A I think I have in my preparation for
18	Correct?	18	this.
19	A Yes.	19	Q Well, it says: The action items from
20	Q Okay. And these were recounting a	20	the meeting. "The FDA has to prepare notes of the
21	note notes that happened that prior Friday,	21	meeting." It's at the very end, the last
22	correct?	22	paragraph.
23	A Yes.	23	A Mm-hmm.
24	Q And so the meeting with the FDA says	24	Q The FDA notes I'm going to show you are
25	May 8th, 2008. Do you see that?	25	Exhibit 56.
	Page 493		Page 495
1		1	
1 2	A Yes.	1 2	(Exhibit No. 56 was marked for
2	A Yes.  Q Okay. Do you agree with me that it's	2	(Exhibit No. 56 was marked for identification.)
2	A Yes.  Q Okay. Do you agree with me that it's likely to be May 8th, 2009?	2	(Exhibit No. 56 was marked for identification.) BY MR. TISI:
2 3 4	A Yes.  Q Okay. Do you agree with me that it's likely to be May 8th, 2009?  A I do agree with you.	3 4	(Exhibit No. 56 was marked for identification.) BY MR. TISI: Q And the FDA meeting notes is like a
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30 (Pages 492 to 495)

	Page 496		Page 498
1	Colors at that point, correct?	1	Q It was requested. An agenda was
2	A Yes.	2	provided to the FDA, correct?
3	Q Okay. By saying that: "Counsel had	3	A I think that's what it says. I don't
4	requested the meeting, but she wanted to make the	4	recall that, but
5	point that the FDA would not talk about the	5	Q Have you seen the agenda in connection
6	Citizen's Petition on tale as it was still under	6	with your preparation today?
7	review."	7	A I don't think so.
8	Do you see that?	8	Q Okay. I didn't see it either. It might
9	A Actually, I'm sorry, where are you	9	be it might be around, but I just maybe I
10	exactly? Oh, there we go. Okay.	10	just didn't see it.
11	Q Do you see that?	11	Was anyone since the agenda, as
12	A Yes.	12	Dr. Bailey pointed out, was involved the
13	Q Okay. Do you remember that	13	Citizen's Petition, right?
14	specifically, that she started out saying, you	14	A That's what it says, yes.
15	know, Great you're all here, but we don't want to	15	Q I'm curious. Did Dr. Bailey propose
16	discuss the Citizen's Petition?	16	that the guy who wrote the Citizen's Petition be
17	A I don't remember it, but I I accept	17	invited to the meeting?
18	that that is what happened.	18	A I don't believe so, no.
19	Q Okay. But then Dr. Bailey corrected	19	Q Do you know whether or not Dr. Epstein
20	her, and said "Dr. Bailey pointed out the	20	or the any of the members of the American
21	agenda that was provided was to discuss the	21	the Cancer Prevention Coalition were asked to
22	information related in the petition."	22	attend the meeting by the FDA or suggested by
23	MR. LOCKE: Objection.	23	PCPC?
24	BY MR. TISI:	24	A Not that I'm aware.
25	Q Correct?	25	Q I mean you are interested in a fulsome
	Page 497		Page 499
1		1	
1 2	MR. LOCKE: Objection to form.	1 2	discussion of the science, right?
2	MR. LOCKE: Objection to form. THE WITNESS: Well, that's what it says,	2	discussion of the science, right?  A I I think for this meeting we were
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Page 500	Page 502
1 to discuss, among other things, that petition,	if you were really interested in the scientific
2 correct?	2 question, why not invite the why not say, Maybe
A Yes.	we should have Dr. Epstein come?
Q And you actually submitted an agenda.	A I think we knew where Dr. Epstein stood,
5 True?	and we disagreed with him.
A That's what it says.	Q Right. So why not have him come to
Q And the agenda was clear that you wanted	7 present his position?
8 to discuss the petition, correct?	A I don't think this was the meeting for
9 A I would assume so based on what this	9 that.
says on the subject matter.	Q Okay. And the FDA initially
Q And you walked in prepared to discuss	expressed its reservation about the meeting,
the petition. You even brought with you	12 correct?
Dr. Muscat and Dr. Huncharek's commissioned work	MR. LOCKE: Objection.
on behalf of the industry, correct?	14 BY MR. TISI:
A That seems to be what it says, yes.	Q It said it said initially said
Q And well, it's not only what it says,	that they didn't want to talk about the pending
it happened, correct?	Citizen's Petition, correct?
18 A Yes.	MR. LOCKE: Objection.
Q And when you're testifying about PCPC	THE WITNESS: And then said that you can
A Yes.	talk to us, but we're not going to talk about
Q this is one of the topics you were	BY MR. TISI:
prepared to talk about.	Q Because you were already there.
A Okay.	A Well, they accepted the meeting, though.
Q Right?	So if there really was an agenda that I'm
A Yes.	sure it would have shown that, and they could have
Page 501	Page 503
1 Q So you walk in there, and did you say to	1 said I mean they would have asked what what
	said I mean they would have asked what what did we want to talk about.
2 them, You know, we really want this is an	did we want to talk about.
them, You know, we really want this is an	<ul><li>did we want to talk about.</li><li>Q Right. But the first sentence here</li></ul>
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32 (Pages 500 to 503)

### Case 3:16-md-02738-MAS-RLS Document 9895-3 Filed 05/30/19 Page 98 of 565 PageID: 71342 Linda Loretz, Ph.D.

Page 504	Page 506
wasn't there or it's just we're working this	A Yes.
through, so we're not going to we're not going	Q Okay. But you wanted to actually get in
3 to give you tell you where we stand right now.	the room and actually speak with them, right?
4 You can talk to us.	4 A Yes.
5 And then later on she asked that we	Q Okay. You know, because because this
6 submit, formally submit our information, which we	6 was important to your members, right?
7 did.	7 A Yes.
	8 Q Okay. The American Cancer Coalition was
<ul><li>Q All right. And asked you some follow-up</li><li>questions, true?</li></ul>	
10 A Yes.	<ul><li>9 representing consumers, right?</li><li>10 MR. LOCKE: Objection.</li></ul>
	11 BY MR. TISI:
Q Okay. Which you did? A Yes.	
Q Do you know whether or not the FDA ever	
reached out to Dr Dr. Epstein or anybody else	THE WITNESS: I'm not sure who they
to say, Look, you know, we would like to get your	represent, but yes.
further input. We met with with the industry	BY MR. TISI:
and their trade organization. They raised some	Q Was there anybody in that room on May 8,
issues about dose response, about contamination	2009, that represented patients, doctors,
with talc, about bio with asbestos, about	consumers?
biologic plausibility, about all the issues that	MR. LOCKE: Other than the FDA?
were in the Citizen's Petition. What is your	THE WITNESS: I was going to say the
response to that?	Commissioner of the FDA, I would
Do you know if that was ever done by the	23 BY MR. TISI:
24 FDA?	Q I'm asking you other than the the FDA
A I think some of reaching out to us, and	25 was trying to decide a question. Correct?
Page 505	Page 507
Page 505  the follow-up questions were ones that were	Page 507
1 the follow-up questions were ones that were	1 A Yes.
<ol> <li>the follow-up questions were ones that were</li> <li>specific to industry, how do you source talc, that</li> </ol>	1 A Yes. 2 Q A scientific question. Right?
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	Page 508		Page 510
1	again sourcing, how do you	1	previously worked, correct?
2	BY MR. TISI:	2	A That's true.
3	Q That came up too.	3	Q In fact, that's why you hired him,
4	A Right, and that's you know, that's	4	right? You hired him because of experience with
5	not a question	5	this particular department.
6	Q But you came in with the epidemiology	6	A We hired him because of his I mean,
7	the first paragraphs here deal with the	7	obviously the fact that he had FDA background
8	epidemiology.	8	was was considered a good thing.
9	For example, it says: "The Council	9	Q In this department, correct?
10	submission and the and the Citizen's Petition	10	A Yes.
11	were briefly summarized. The response was	11	Q And you hired him knowing full well that
12	prepared by two epidemiologists, Dr. Michael	12	talc was a very important issue that was coming
13	Huncharek and Dr. Muscat, with a cover letter from	13	what that might be dealt with by this department,
14	the Council. In their document Huskarek	14	correct?
15	Huncharek and Muscat provide a summary of each of	15	MR. LOCKE: Objection.
16	the 12 publications cited in the petition."	16	THE WITNESS: As far as I know, and I
17	Do you see all that?	17	had nothing to do with the hiring of Dr. Bailey,
18	A Yes.	18	it wasn't about a specific issue at all. It
19	Q "It was noted that half the publications	19	was I mean, the general fact was he had a
20	are either reviews or do not provide new data or	20	wonderful background with FDA and cosmetics, and
21	address aspects of ovarian cancer or talc but do	21	that made him a valuable employee to the Council,
22	not provide a link between the two. The	22	to CTFA.
23	submission then provides an overall summary of	23	BY MR. TISI:
24	epidemiology relating to talc and ovarian cancer,	24	Q Now, do you know whether or not prior to
25	noting that the excess risk is small and often not	25	this meeting
25		23	-
	Page 509		Page 511
		_	A TOTAL CONTRACTOR OF THE CONT
1	statistically significant, overall lacks	1	A This meeting.
2	dose-response relationship, or in some cases shows	2	Q This meeting, May 9th May 8th
2	dose-response relationship, or in some cases shows an inverse dose-response relationship, lacks a	2	Q This meeting, May 9th May 8th A 2009.
2 3 4	dose-response relationship, or in some cases shows an inverse dose-response relationship, lacks a biological plausible mechanism, and that the	2 3 4	<ul><li>Q This meeting, May 9th May 8th</li><li>A 2009.</li><li>Q 2009.</li></ul>
2 3 4 5	dose-response relationship, or in some cases shows an inverse dose-response relationship, lacks a biological plausible mechanism, and that the exposure data is limited."	2 3 4 5	<ul> <li>Q This meeting, May 9th May 8th</li> <li>A 2009.</li> <li>Q 2009.</li> <li>This was a formal meeting that was set</li> </ul>
2 3 4 5 6	dose-response relationship, or in some cases shows an inverse dose-response relationship, lacks a biological plausible mechanism, and that the exposure data is limited."  There was a discussion of all that	2 3 4 5 6	Q This meeting, May 9th May 8th A 2009. Q 2009. This was a formal meeting that was set up by Dr. Bailey. Correct?
2 3 4 5 6 7	dose-response relationship, or in some cases shows an inverse dose-response relationship, lacks a biological plausible mechanism, and that the exposure data is limited."  There was a discussion of all that stuff, right?	2 3 4 5 6 7	Q This meeting, May 9th May 8th A 2009. Q 2009. This was a formal meeting that was set up by Dr. Bailey. Correct? A I think you would call it that.
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	Page 512		Page 514
1	to a call that was made, conversations that had	1	requesting to have a warning label placed on
2	been had?	2	products containing" there is no word, but I
3	A From related to the petition?	3	think it's
4	Q Mm-hmm.	4	A Right.
5	A Sometime between when it was filed	5	Q involving talc.
6	and	6	A Right.
7	Q Mm-hmm.	7	Q "Here is an update on that activity.
8	A You can refresh my memory, but	8	Kathy Wille of J&J informed me that at a recent
9	nothing I'm not thinking of anything, no.	9	science meeting in Washington, D.C., she had a
10	(Exhibit No. 57 was marked for	10	side conversation with a key figure from the FDA
11	identification.)	11	cosmetic group responsible for responding to the
12	BY MR. TISI:	12	Citizen's Petition. He indicated that the FDA
13	Q Let me show you Exhibit No. 57.	13	would rule against the petition and would
14	This is not a PCPC document. I'm seeing	14	require would not require warning labels on
15	whether this refreshes your recollection.	15	cosmetic products, but the FDA is looking for
16	Now, at the very bottom, and I I'm	16	scientific support from industry that would help
17	going to ask you to read it, but I'm just going to	17	justify their position. She suggested that there
18	kind of set the table for you.	18	be a collective group working to have comments
19	A Very bottom of the second page?	19	submitted to the FDA. Principal among these
20	Q So first page.	20	efforts will be comments that Dr. Muscat and
21	A Okay.	21	Huncharek are co-developing.
22	Q There's an e-mail from Craig Bernard to	22	"In order to orchestrate the completion
23	Mark Zamek at J&J I mean at Rio Tinto. And Rio	23	of these comments, I have been asked by J&J to
24	Tinto is is Imerys as well, correct?	24	meet with them, along with Muscat and Huncharek,
25	A I believe so, yes.	25	at their headquarters in New Jersey on Wednesday,
	Page 513		Page 515
1	Q And it's referring to a meeting with	1	November 19th, in order to review the comments
2	J&J. Do you see that?	2	before being provided to Personal Care Products
3	A Yes.	3	Council."
4	Q Okay. If you would read it to yourself,	4	Do you see that?
5	please, and then we can	5	A Yes.
6	A Mm-hmm.	6	Q Okay. I read that correctly, right?
7	Q we can go off the record if you want.	7	A I believe so, yes.
8	It doesn't matter to me, but you can read it to	8	Q All right. This would suggest that
9	yourself.	9	there was another informal contact with the office
10	MR. TISI: We can go off the record.	10	of colors, fragrance and I'm sorry. I'm
11	MR. LOCKE: No. Let's stay on the	11	blanking. Office of
12	record.	12	A Cosmetic and Colors.
13	MR. TISI: Okay.	13	Q Cosmetics and Colors.
14	THE WITNESS: (Peruses document.)	14	Are you aware of it? Does this refresh
15	BY MR. TISI:	15	your recollection?
16	Q I'm really going to ask you about that	16	MR. LOCKE: Objection.
17	first big paragraph.	17	BY MR. TISI:
18	A Okay.	18	Q Does this refresh your recollection?
	Q Okay. First of all, the subject matter	19	A No.
19		20	Q If there was a side conversation about a
20	is "Meeting with J&J," correct?		
20 21	A Yes.	21	Citizen's Petition, in your experience being a
20 21 22	A Yes. Q Okay. And the first sentence says:	22	liaison with the FDA, would that be inappropriate?
20 21 22 23	A Yes. Q Okay. And the first sentence says: "You'll recall a couple of months ago we met with	22 23	liaison with the FDA, would that be inappropriate?  MR. LOCKE: Objection.
20 21 22	A Yes. Q Okay. And the first sentence says:	22	liaison with the FDA, would that be inappropriate?

35 (Pages 512 to 515)

	Page 516		Page 518
1	THE WITNESS: I I mean I'm not a	1	it was fairly late I mean, I think it was
2	liaison with the FDA. I I don't know if this	2	reasonably close to when the comments were
3	is referring to the meeting that we had with the	3	submitted.
4	FDA or a different meeting.	4	BY MR. TISI:
5	BY MR. TISI:	5	Q Do you know?
6	Q Well, the date the date of it is	6	A No.
7	November 3rd, 2008, so this would have been a good	7	Q Did you investigate that?
8	six months before your meeting	8	I mean, one of the categories very
9	A Oh, okay.	9	specific in our notice of deposition were the
10	Q with the FDA.	10	circumstances surrounding the Citizen's Petition.
11	A Oh, I'm sorry.	11	Did you that's why I asked you in the early
12	I I mean I just can't comment on	12	A Mm-hmm.
13	this. I don't know if this happened. I don't	13	Q Did you interview or look specifically
14	know if it was you know, if it's characterized	14	at the notes pertaining to the Citizen's Petition
15	correctly.	15	and perhaps speak to Dr. Bailey about what
16	Q Well, I'm going to ask you this	16	happened?
17	question. You don't have knowledge of it, I	17	A Did I speak to him at the time?
18	accept you at your word.	18	MR. LOCKE: Objection. It's a compound
19	If this happened, in your experience	19	question.
20	having side conversations with FDA people about	20	BY MR. TISI:
21	issues that are pending before the FDA, is that	21	Q Okay. Did you review all the documents
22	appropriate?	22	at your possession relating to the preparation of
23	MR. LOCKE: Objection.	23	the Citizen's Petition?
24	MS. FRAZIER: Object to form.	24	A In preparation for this?
25	MR. LOCKE: And beyond the scope.	25	Q Yes.
	Page 517		Page 519
1	THE WITNESS: I can't imagine an FDA	1	A I'm not sure.
2			11 III not bare.
	person saying something like I mean that would	2	Q All right. Did you ask to see the notes
3	seem to me	2 3	
3 4			Q All right. Did you ask to see the notes
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4	seem to me BY MR. TISI:	3 4	Q All right. Did you ask to see the notes from the other defendants that might help you understand better what PCPC's role with respect to
4 5	seem to me BY MR. TISI: Q Wrong.	3 4 5	Q All right. Did you ask to see the notes from the other defendants that might help you understand better what PCPC's role with respect to the Citizen's Petition was?
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36 (Pages 516 to 519)

Page 520 Page 522 1 1 THE WITNESS: I can tell you what I Q So let me show you an e-mail dated --2 think my recollection is, that this was not a 2 58, this is May 2008, right after the Citizen's 3 3 longstanding thing. This was a -- J&J had -- had Petition was filed. It's an internal -- this 4 worked on having a -- Drs. Muscat and Huncharek 4 would have been a whole year before the meeting at 5 5 prepare a review, a current review of the the -- at the FDA. 6 literature, and thought that that would be 6 And from Kathleen Wille, and it's an 7 appropriate to submit. And I suspect that all 7 internal document. I don't expect that you would 8 8 have seen it in realtime. But it's talking about happened fairly soon before we actually submitted 9 9 the Citizen's Petition and the next steps. 10 10 BY MR. TISI: Do you see it? 11 Q Now, prior to this you had fairly 11 A I'm just reading through now. 12 consistent -- on this issue, you were -- as best I 12 (Peruses document.) Okay. 13 can tell from looking at the overall records that 13 Q Okay. And so just as you read this, 14 were produced in this case, and you can correct me 14 what's happening is the Citizen's Petition is 15 if I'm wrong, as I look at the decade or so prior 15 filed by Dr. Epstein, and there's kind of a 16 to this, you were the primary contact on this 16 mobilization of effort in -- in how to respond to 17 17 issue. that, and it's entitled "Next Steps." Do you see 18 A I would say myself and Dr. McEwen. 18 that? 19 Q Okay. Dr. Bailey really wasn't hands on 19 A I'm not sure where -with this issue over the -- as compared to you, 20 20 Q Second page. 21 21 22 22 Q Okay. And underneath that, one of the A Well, I guess I think our -- you know, our biggest involvement, PCPC's biggest 23 things they -- two things -- there are three 23 24 involvement, biggest effort related to NTP, and 24 things they identify. Secure funding and engage 25 Dr. Bailey wasn't there at the time. 25 experts, and that would be Huncharek and Muscat Page 521 Page 523 1 Q Okay. And the Citizen's Petition as 1 that's named here, and PCPC ultimately paid for 2 well. 2 that, right? 3 A Right, but it -- it wasn't -- we weren't 3 A Yes. doing multiple submissions and presenting at Q Okay. Number 2, "Engage internal 4 4 5 stakeholders." Do you know whether or not any meetings, and that sort of stuff. So it was --5 6 Q Right. But in terms of -- and, you 6 public relations people were -- were contacted in 7 know, we looked at examples here, but, you know, 7 connection with the Citizen's Petition? 8 you were kept up to date on the IARC issues, you 8 A I'm not aware --9 had been communicating with Bob Glenn at -- at --9 MR. LOCKE: Objection. You're referring 10 I mean I've seen a bunch of them, I could pull 10 to J&J -- you're asking the witness about J&J? 11 MR. TISI: No, I did not. them out for you. 11 12 But to the extent that the -- the other 12 BY MR. TISI: 13 defendants in this case, J&J and Imerys, were 13 Q I asked, are you aware of any public 14 contacting PCPC about issues related to talc, you 14 relations people for anybody that was contacted in 15 were prime -- the primary person that would be 15 connection with this Citizen's Petition? 16 their liaison. 16 A I guess I could only answer for PCPC, 17 A Probably. That's probably true. 17 and I'm not aware of any. 18 Q Okay. Until the Citizen's Petition 18 Q Okay. But the third is what I'm most was -- was filed, do you know that they interested in, "Determine level of external 19 19 20 contacted -- they wanted to contact Dr. Bailey? 20 support." 21 21 MR. LOCKE: Objection. The first is John Bailey. It says: 22 THE WITNESS: No, I didn't. 22 "John Bailey of the Personal Care Products Council 23 (Exhibit No. 58 was marked for 23 is out of the office until the next week, 24 24 June 2nd. We will ascertain their plans to identification.) 25 BY MR. TISI: 25 respond."

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	Page 524		Page 526
1	Do you see that?	1	Counsel.
2	A Yes.	2	MR. LOCKE: Okay, good.
3	Q Okay. It didn't say, We're contacting	3	BY MR. TISI:
4	Linda Loretz, are they?	4	Q Tell me everything that you know
5	A That might be because it's Kathy Wille.	5	happened with respect to the development of the
6	I mean it just kind of depends who within	6	response to the Citizen's Petition.
7	Johnson & Johnson is is responding.	7	I know you said it was initiated by J&J.
8	Q So do you know whether or not in this	8	Do you know that Imerys had some input we saw a
9	time frame this is a full year before the	9	meeting that with Drs. Huncharek and Muscat
10	meeting, more than with the FDA and more than a	10	and and Imerys in November. Were you at that
11	year before the formal response was filed in July	11	meeting?
12	of 2009.	12	A No.
13	Do you know whether or not at this time	13	Q You know did you know it happened?
14	frame, J&J had been able to contact Dr. Bailey,	14	A I don't believe so. If I I don't
15	who again had been the prior director of the	15	recall it, no.
16	division?	16	Q Were you given an opportunity to review
17	A Yeah, I don't know what discussions went	17	the the Citizen's Petition that was actually
18	on with	18	filed on on PCPC's behalf?
19	Q I don't mean to be factitious about it,	19	A I I'm sure I was in the sense that
20	but wouldn't it make sense to actually if you	20	obviously if it was something we have had an issue
21	are here to testify on that issue, to actually	21	with, we wouldn't have submitted it. So I'm going
22	speak to Dr. Bailey	22	to say yes.
23	MR. LOCKE: Objection.	23	Q And so when you say it was it was
24	BY MR. TISI:	24	drafted by somebody else, it went out under PCPC's
25	Q about that issue?	25	name, and to the extent that you're here as a
			·
			Daga E271
1	Page 525	1	Page 527
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2	MR. LOCKE: Objection. By the way, it also says, "We will then	2	representative of PCPC, you agree with everything that's in that document.
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Page 528 Page 530 1 MS. FRAZIER: Object to form. 1 that says "Meta-Analysis Research Group" across 2 THE WITNESS: No. 2 the top, right? 3 3 A Yes. BY MR. TISI: 4 Q And when a -- when a company -- I mean, 4 Q Okay. Did you do any due diligence as 5 5 to -- as to who Meta-Analysis Research Group was? when a company commissions a report like this, 6 doesn't the company usually reserve the right to 6 MR. LOCKE: Objection. Asked and 7 review it and make comments and edits before it's 7 answered. 8 8 THE WITNESS: We put faith in the submitted? 9 MR. LOCKE: Objection. Beyond the 9 epidemiologists as knowledgeable epidemiologists. 10 10 BY MR. TISI: scope. 11 BY MR. TISI: 11 Q Okay. Without doing your due diligence. 12 MR. LOCKE: Objection. 12 Q Typically? A I mean that --13 13 BY MR. TISI: 14 MR. LOCKE: Objection. 14 Q You did not investigate Dr. Huncharek 15 THE WITNESS: -- that brings up like us 15 and Muscat and what their relationship was, where 16 doing that, PCPC, you know, talc, other topics, 16 their funding came from, and how much time they 17 17 whatever, and yes, but I think when you're hiring spent on these issues, did you? MR. LOCKE: Objection. Mischaracterizes 18 reputable people, they're not going to let you 18 19 change their conclusions. I mean, you might have 19 testimony, asked and answered. 20 THE WITNESS: We accepted them because 20 edits, typos, clarity needed. I mean... 21 BY MR. TISI: 21 of their epidemiology expertise. 22 22 Q Right. Focus. BY MR. TISI: Q Did you have an opportunity to review 23 23 A Yeah. 24 Q Right. But -- but -- I mean that 24 this before it went in? 25 presumes that these are reputable people in part, 25 A As I say, I'm sure I did. Page 529 Page 531 1 1 Q Okay. Have you had any -- do you have don't you think? 2 MR. LOCKE: Objection. 2 any dispute that this is PCPC's response, that 3 THE WITNESS: It does. 3 PCPC agrees with the content? 4 BY MR. TISI: 4 MR. LOCKE: Objection. Asked and 5 5 Q Did you -- did you do -- I mean that's answered. The witness testified it was submitted 6 why I brought the brochure out there. You didn't б by the two epidemiologists. 7 do any due diligence as to who these people were 7 MR. TISI: I -- I'm not going to ask you 8 8 to characterize it. Your not under oath, Counsel. and what their stake was in this issue, did you? 9 MR. LOCKE: Objection. Mischaracterizes 9 I appreciate you schooling me, but honestly. 10 10 testimony. BY MR. TISI: 11 THE WITNESS: Yeah. 11 Q Is this PCPC's document? 12 MR. TISI: Whose testimony? 12 MR. LOCKE: We're just going to stick MR. LOCKE: Hers. 13 13 with the prior answer then. 14 BY MR. TISI: 14 BY MR. TISI: 15 Q Did you do any due diligence into who 15 Q Is this PCPC's document? Meta-Analysis Research Group is and to where they 16 16 MR. LOCKE: Objection. Asked and got their major funding? 17 17 answered. Let's move on. 18 MR. LOCKE: Objection. Asked and MR. TISI: No, we're not moving on. I 18 answered. We've covered this. want an answer to that question. 19 19 20 MR. LOCKE: You've answered -- she's BY MR. TISI: 20 21 Q Did you do it? 21 answered it three times. 22 A We had worked with Dr. Muscat before. 22 BY MR. TISI: 23 Q I -- I didn't ask you that question. 23 Q Do you -- do you -- is this PCPC's -- I 24 This was written on behalf of Meta-Analysis 24 mean, for example, we read a sentence at the very 25 Research Group, correct? It's got the big logo 25 beginning in the Introduction section that says,

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Page 532 Page 534 Q Not a hundred percent consistent, but 1 We --1 2 MR. LOCKE: You're talking about the 2 is --3 3 instruction that was written by the two A But, yes. 4 4 Q - is a hundred percent consistency scientists? 5 MR. TISI: The -- I don't know if that's 5 required? 6 6 written by the two scientists. That's my A No. 7 7 Q Okay. So there was consistency across question. 8 MR. LOCKE: Well, it says "prepared" --8 studies. MR. TISI: Honestly, Counsel. 9 9 Now, arguing against causal association, Dr. Bailey, on behalf of the PCPC, which you are 10 MR. LOCKE: No, honestly. 10 11 MR. TISI: Honestly, I'm asking the 11 here for -question. Okay. There's been a lot of 12 12 A Yes. 13 ghostwriting in this case. 13 Q -- says: "There is a lack of a clear MR. LOCKE: Objection. dose-response relationship." Correct? 14 14 A Yes. 15 BY MR. TISI: 15 16 Q "Given the multiple implications of such Q And even posits that some epidemiologic 16 studies suggest an inverse association. Correct? 17 warnings, the Personal Care Products Council 17 18 sought an evaluation of the validity of the 18 A Correct. 19 scientific facts underlying this request." Right? Q Now, as a toxicologist, if you see an 19 Do you know whether or not this 20 20 inverse association with the disease, doesn't it 21 document, Exhibit No. 20 -- 43, is the report 21 raise the suggestion that this is a protective -submitted by PCPC and it is PCPC's position, 22 22 may have a protective effect? correct? MR. LOCKE: Objection. Beyond the 2.3 23 24 MR. LOCKE: Objection. Compound 24 scope, calls for expert testimony. 25 25 BY MR. TISI: question. Page 533 Page 535 1 THE WITNESS: I believe this is the 1 Q I mean there might be reasons why 2 document we submitted. 2 that -- why that is seen, correct? 3 BY MR. TISI: 3 MR. LOCKE: Same objection. Q Okay. All right. Let's talk about it THE WITNESS: In theory, that's possible 4 4 5 5 for a moment. if there's consistency. 6 The summary provided by Dr. Bailey in б BY MR. TISI: the cover letter says: "The review concludes that 7 7 Q I mean if this was a protective of the weak epidemiologic association is unlikely to 8 ovarian cancer, you may have found a miracle, 8 9 be causal." 9 right? 10 Do you see that? 10 A Well, I would go into the causality. It would work the same way for protective effect. 11 A Yes. 11 12 MR. LOCKE: What page are you at? 12 Q You didn't believe that there was an MR. TISI: Page 2, Dr. Bailey's letter. inverse -- there was an inverse relationship 13 13 14 MR. LOCKE: Okay. between ovarian cancer and talc, did you? 14 A That's not what it says. Some 15 BY MR. TISI: 15 16 Q Putting aside the characterization of 16 studies --"weak," which we can talk about in a moment, do Q Suggest that. 17 17 you believe that there was an epidemiologic A -- showed that. 18 18 association seen across studies? Q And if that were really something that 19 19 was seen in some studies, as a toxicologist and as 20 A It's not --20 21 somebody who represents the talc industry, that 21 MR. LOCKE: Objection. Beyond the 22 would be something that would be really an 22 interest to you, wouldn't it? 23 THE WITNESS: Not a hundred percent 23 24 A I don't read it that way at all. The 24 consistent, no. BY MR. TISI: 25 25 point of saying that some studies showed an

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Page 536 Page 538 1 1 inverse relationship cast doubt on the causality. Q -- that are different than the 2 Q Okay. Well, there are biases that might 2 explanation that Drs. Muscat and Huncharek said on 3 suggest that -- why that would occur particularly 3 the -- on behalf of the industry. 4 with a disease like cancer. Are you familiar with 4 A I think our --5 5 survival bias? Have you ever heard of that? MR. LOCKE: Objection. 6 MR. LOCKE: Objection. Beyond the 6 THE WITNESS: I think our comments were 7 7 posted, though, so somebody could see that they scope. 8 THE WITNESS: I'm not sure what that 8 were --9 phrase means. 9 BY MR. TISI: 10 BY MR. TISI: 10 Q Do you know whether or not Dr. Epstein 11 Q Okay. Did you ever -- on behalf of the 11 or anybody else was contacted and say, These PCPC, did you ever ask whether or not there would are -- these are the contacts. Do you want to 12 12 13 be explanations consistent with causation by which 13 respond? Do you know whether they even checked 14 you might see an inverse dose-response 14 the website? 15 relationship? 15 A Well, I don't, but they had the right to 16 A I think -- I mean, as far as the 16 check -- I mean --17 scientist- -- the scientific analysis we left to 17 Q Right. 18 18 A -- the same way as a Citizen Petition the epidemiologists. 19 Q Well, I mean, pardon me for being -- for 19 would be posted, the comments received would be 20 being direct about this. 20 posted. 21 Before this was actually filed, you and 21 Q But not everybody has a former director 22 of the division that considers this work for them all of these -- these companies marched into the 22 23 23 FDA on the Citizen's Petition issue on May -- in like you did, correct? 24 May of 2009 to talk about the epidemiology in 24 MR. LOCKE: Objection. 25 part. Correct? 25 BY MR. TISI: Page 537 Page 539 1 A I think the talk on that was fairly 1 Q Do you know whether or not Epstein had 2 limited. I mean, the parts I remember from that 2 any connection with the FDA? 3 meeting had more to do with talking about sourcing 3 I mean, you have to admit having 4 and that sort of thing. I -- and again, as -- as 4 Dr. Bailey is a pretty -- is a pretty important 5 the meeting minutes say, FDA wasn't engaging us in 5 connection to the FDA, don't you think? 6 discussion. They were going to let us say our 6 MR. LOCKE: Stop. Which question do you 7 7 piece -want her to answer? 8 8 Q Right. MR. TISI: That one. 9 A -- and then said, Please submit that so 9 BY MR. TISI: 10 that we can actually read and consider it. 10 Q That's a pretty important connection to 11 Q And there was no opportunity for 11 the FDA, having somebody who worked for the 12 doctor -- Dr. Epstein or anybody else to come in 12 division, correct? and say, You know, okay, we saw that in the -- in 13 13 MR. LOCKE: Objection. 14 the medical literature. This is a possible 14 THE WITNESS: I mean, I think as I said 15 explanation as to why that is. 15 before, he was -- he was hired for his 16 MR. LOCKE: Objection. 16 understanding of the FDA, for his experience. 17 BY MR. TISI: 17 BY MR. TISI: 18 Q There was no other opportunity in the 18 Q Not his contacts? 19 four years that this was pending for -- for A For knowing the people, that's -- that's 19 20 anybody to come in and say -- and say, You know 20 okay. That doesn't mean they're going to --21 what, we -- we noted that there's an inverse 21 Q Right. 22 relationship, but these are possible explanations 22 A -- do things differently because they 23 23 know the guy. 24 24 Q Do you know -- do you know whether or MR. LOCKE: Objection. 25 BY MR. TISI: 25 not Dr. Epstein's group had any similar

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	Page 540		Page 542
1	relationship with the FDA?	1	"An additional limitation on existing literature
2	A I I do not.	2	with the proposed talc/ovarian cancer association
3	Q So the next thing that Dr. Bailey on	3	is a lack of any known biological mechanism."
4	behalf of the PCPC says that: A plausible	4	Do you see that?
5	econom biologic mechanism is lacking to	5	A I'm sorry. Okay. Now I'm on the
6	explain a causal relationship."	6	right paragraph, I think. Yes.
7	Do you see that?	7	Q Okay. Next paragraph down, and feel
8	A Yes.	8	free to read it if you wish. I'm not I assume
9	Q It talks about potential confounding	9	you read this before you came in here today,
10	factors, correct?	10	right?
11	A Yes.	11	A Yes.
12	Q And it talks about summarizes all	12	Q Okay. "He makes the point that
13	of all of the issues?	13	initially Cramer, et al.," and that's
14	A Yes.	14	Dr. Cramer we talked about before who published
15	Q All right. Now, one of the things that	15	epidemiology several epidemiology studies, in
16	the FDA was very concerned about at the meeting	16	fact, right?
17	that you attended with them was whether or not	17	A Yes.
18	cosmetic talc	18	Q He's one of the people who looked at the
19	The stuff that comes in the bottle,	19	medical literature and thought there was a causal
20	right?	20	inference, right?
21	A Yes.	21	MR. LOCKE: Objection.
22	Q had constituents that might explain	22	THE WITNESS: Yes.
23	the increased relative risks. They talk about	23	BY MR. TISI:
24	asbestos, correct for example, correct?	24	
25	A I think they talked about purity, yes.	25	Q Okay "and sought to draw an analogy
23	, , , , , , , , , , , , , , , , , , ,	23	and sought to draw an analogy
	Daga E/1		Daga E42
1	Page 541	1	Page 543
1	Q Okay. And and that's an important	1	between talc and fibrous asbestos, the latter
2	Q Okay. And and that's an important issue, don't you think?	2	between talc and fibrous asbestos, the latter being a known and well-described carcinogen."
2	Q Okay. And and that's an important issue, don't you think?  A Sure.	2 3	between talc and fibrous asbestos, the latter being a known and well-described carcinogen." First of all, that's true, right?
2 3 4	Q Okay. And and that's an important issue, don't you think?  A Sure.  Q And one of the things that has made the	2 3 4	between talc and fibrous asbestos, the latter being a known and well-described carcinogen." First of all, that's true, right? A I'm sorry. I'm
2 3 4 5	Q Okay. And and that's an important issue, don't you think?  A Sure.  Q And one of the things that has made the points that is made by Dr. Bailey on behalf of the	2 3 4 5	between talc and fibrous asbestos, the latter being a known and well-described carcinogen." First of all, that's true, right? A I'm sorry. I'm MR. LOCKE: What's your question?
2 3 4 5 6	Q Okay. And and that's an important issue, don't you think?  A Sure. Q And one of the things that has made the points that is made by Dr. Bailey on behalf of the PCPC and Dr. Muscat and Huncharek is that there	2 3 4 5 6	between talc and fibrous asbestos, the latter being a known and well-described carcinogen." First of all, that's true, right? A I'm sorry. I'm MR. LOCKE: What's your question? BY MR. TISI:
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2 3 4 5 6 7 8 9 10 11	Q Okay. And and that's an important issue, don't you think?  A Sure.  Q And one of the things that has made the points that is made by Dr. Bailey on behalf of the PCPC and Dr. Muscat and Huncharek is that there was no biologically plausible mechanism because talc is not known to be a carcinogen, pure talc.  A Okay.  Q Is that true? I mean, I could point it out. Let's go to the page let's go. Go to page 25 of the of Dr. Huncharek's report	2 3 4 5 6 7 8 9 10 11	between talc and fibrous asbestos, the latter being a known and well-described carcinogen." First of all, that's true, right? A I'm sorry. I'm MR. LOCKE: What's your question? BY MR. TISI: Q I said I said asbestos "fibrous asbestos is a known and well-described carcinogen." A Where does it say that? Q First sentence, the last full paragraph starting "Initially."
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. And and that's an important issue, don't you think?  A Sure.  Q And one of the things that has made the points that is made by Dr. Bailey on behalf of the PCPC and Dr. Muscat and Huncharek is that there was no biologically plausible mechanism because talc is not known to be a carcinogen, pure talc.  A Okay.  Q Is that true? I mean, I could point it out. Let's go to the page let's go. Go to page 25 of the of Dr. Huncharek's report Muscat and Huncharek's report.  A Okay.  Q Could you read let's put up the last two paragraphs.  Are you there? It's page 25 of 28 of 39.  Okay. Now it says here: "Initially Cramer," and that's  A What page are you on?  Q Page 20 it's 25 on the top. It says	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	between talc and fibrous asbestos, the latter being a known and well-described carcinogen." First of all, that's true, right? A I'm sorry. I'm MR. LOCKE: What's your question? BY MR. TISI: Q I said I said asbestos "fibrous asbestos is a known and well-described carcinogen." A Where does it say that? Q First sentence, the last full paragraph starting "Initially." A Okay. Oh, okay it. Got it. Sorry. Very first sentence. Q And you agree with that, right, because you sent that A Yes. Q on behalf of the PCPC? Okay. And he makes the point at the end that: "Prior to the 1970s, some products may have contained some asbestos." Correct? A Correct.

42 (Pages 540 to 543)

Page 544 Page 546 1 Q Okay. And it says: "Clearly such 1 BY MR. TISI: 2 products could possibly represent a carcinogenic 2 Q Okay. No detectable asbestos or no 3 risk secondary to asbestos contamination." 3 asbestos? A I mean, there is a specification that's 4 4 Correct? 5 A That's what it says. 5 no detectable. 6 Q Okay. And so we can agree that asbestos б Q Different question. 7 contamination could in fact be a basis of talcum 7 My question is, are you representing to 8 8 powder products -- a biologically plausible the -- is this being represented to the FDA that 9 mechanism by which talcum powder products may 9 there is -- that asbestos was eliminated? 10 cause ovarian cancer. Correct? 10 A I mean, I think the FDA knows as much 11 MR. LOCKE: Objection. Beyond the 11 about what's going on with asbestos because they 12 12 were involved in the -- in the specification scope. 13 THE WITNESS: Yeah, I mean, I think what 13 that --14 14 this is actually saying is -- is that's not talc Q In the 1970s? 15 MR. LOCKE: Let her --15 per se. 16 BY MR. TISI: 16 THE WITNESS: And understand there was a 17 Q Right. But we're talking about --17 detection limit. 18 that's why I made the point in the very beginning 18 BY MR. TISI: 19 of saying that -- we're talking about what's in 19 Q Honestly, that -- that's not my 20 the bottle, right? 20 question. Okay? 21 A Right. 21 MR. LOCKE: Let her finish her answer, 22 Q And so if talcum powder products have 22 and then you can ask --23 23 asbestos in it, that would be a biologically BY MR. TISI: 24 plausible mechanism, and Drs. Huncharek and Muscat 24 Q My question -- my question is this --25 assumed that there was none. That was a predicate 25 this report assumes that asbestos had been Page 545 Page 547 1 eliminated from talcum powder products since 1970. 1 for their statement. 2 Because the next paragraph, it says: 2 True or not true? 3 "Since the early '70s, the relevant industries 3 MR. LOCKE: Objection. THE WITNESS: I -- I think it's like 4 voluntarily eliminated asbestos from contamination 4 5 from talc products." 5 anything else, at some detection limit. I mean 6 Do you see that? 6 every contaminant has a detection limit. So I 7 A Yes. 7 think that's implied. 8 8 Q Okay. So the assumption being that BY MR. TISI: Q Okay. And if asbestos -- let's assume 9 there was no asbestos that had been eliminated, 9 10 10 that you use the right test, right? I mean, you correct? 11 could use -- you could use a -- if you used the 11 A That's what it says. 12 Q Okay. What does the word "elimination" 12 wrong test and you don't -- it may go undetected, 13 mean to you? 13 14 MR. LOCKE: Objection. 14 A Well, as is true for any analysis. 15 THE WITNESS: Well, it was the '70s when 15 Q Correct. Okay. 16 the asbestos issue was raised, and there was a lot 16 So my quest- -- my question is when you make the -- the statement does not say -- because 17 of work by the industry to develop a specification 17 that -- that said that there would be no everybody had an opportunity to look at this 18 18 19 19 detectable asbestos. before it went in. 20 20 When this statement is made to the FDA. BY MR. TISI: 21 Q Right. And so the -- but my question 21 it says asbestos had been eliminated. True? is, what does the word "elimination" mean to you? 22 22 A Again, I think you can argue what 23 MR. LOCKE: Objection. 23 that -- what that word -- what is meant by that 24 THE WITNESS: I think in this context it 24 word here. 25 means no detectable asbestos. 25 Q Okay. Well, we can agree that if there

43 (Pages 544 to 547)

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Page 548
                                                                                                          Page 550
                                                              1
 1
       was some asbestos in some -- in talcum powder
                                                                          MS. FRAZIER: Object to form.
 2
       products, that would provide a biologically
                                                              2
                                                                    BY MR. TISI:
 3
       plausible mechanism which would explain the
                                                              3
                                                                       Q Did you know that?
 4
       increased risk, right?
                                                              4
                                                                       A I'm not sure what that means.
 5
             MR. LOCKE: Objection. Beyond the
                                                              5
                                                                       Q Meaning that they had talc samples from
 6
                                                              6
                                                                    the mines, from the -- from -- from -- that the
       scope.
 7
       BY MR. TISI:
                                                              7
                                                                    grade of talc that was used in the talcum powder
 8
          Q And that's what the FDA was asking
                                                              8
                                                                    products to actual physical bottles that were
 9
       about, right?
                                                              9
                                                                    returned by consumers.
10
                                                            10
             MR. LOCKE: Objection.
                                                                          Did you know that?
11
       BY MR. TISI:
                                                            11
                                                                       A I guess no, not really.
12
                                                            12
          Q Because on the May 8th -- let me
                                                                       Q I mean, one of the things -- if the FDA
13
       rephrase the question.
                                                            13
                                                                    was asking you questions about whether or not what
14
                                                            14
                                                                    was in the bottle might contain things other than
             On the May 8th meeting with -- with you
15
       all, and you made the point several times, in
                                                            15
                                                                    pure talc, were you curious as the entity to say,
                                                            16
16
       addition to the epidemiology, the FDA wanted to
                                                                    Hey, guys, do you have any samples around we can
                                                            17
17
       know just how pure talcum powder products were.
                                                                    test?
18
          A They wanted to know -- they raised
                                                            18
                                                                       A I mean, I --
19
       questions about sourcing and testing and how do
                                                            19
                                                                          MR. LOCKE: Objection.
20
       you find the mines and -- and that type of stuff.
                                                            20
                                                                          THE WITNESS: -- think we had -- we had
21
          Q Because they wanted to know how -- well,
                                                            21
                                                                    worked with FDA and companies looking at that
22
       you knew the -- the reason why they were asking
                                                            22
                                                                    question, if we're talking about asbestos back in
23
       that question because they wanted to know what was
                                                            23
                                                                    the '70s.
24
       in the bottle.
                                                            24
                                                                    BY MR. TISI:
25
          A Yes. They were trying to understand --
                                                            25
                                                                       Q Right. And you also made the point that
                                             Page 549
                                                                                                          Page 551
 1
       right.
                                                              1
                                                                    some of those specifications were decades old,
 2
          Q Right. This was not pharmaceutical
                                                              2
                                                                    right? And one of the things that Dr. Bailey
 3
       grade talc. This was cosmetic talc, right?
                                                              3
                                                                    said, that they would be willing to look at -- at
 4
             MR. LOCKE: Objection.
                                                                    tightening up those specifications, right?
                                                              4
 5
                                                              5
                                                                          MR. LOCKE: Objection.
             THE WITNESS: I think it's basically the
 6
       same as pharmaceutical grade talc, but yes.
                                                              6
                                                                          THE WITNESS: I think he did. I mean,
                                                              7
 7
       BY MR. TISI:
                                                                    there was always an openness -- obviously, FDA was
 8
                                                              8
                                                                    welcome to do their own specification, but I don't
          Q But the point is there -- there are a
 9
       lot of things -- so -- so what the FDA really
                                                              9
                                                                    think methodologies had substantially changed.
10
       wanted to drill down to here is -- I know you guys
                                                            10
                                                                    BY MR. TISI:
11
                                                            11
                                                                       Q Well, do you know that?
       talked about, you know, talc as a molecule and
12
       whether or not it can cause ovarian cancer, and
                                                            12
                                                                       A Yes, actually, I think I could say I do.
                                                                   I think our specification is essentially the same
13
       you addressed that issue, but are there other
                                                            13
14
       things in the bottle that might explain this
                                                            14
                                                                    as what the USP uses essentially. And I know like
                                                                    ASTM was looking at it, but they haven't changed
15
       increased risk? They asked you that question,
                                                            15
16
       right?
                                                            16
                                                                    anything or promulgated a new specification.
             MR. LOCKE: Objection.
                                                                       Q So the question -- the question that I
17
                                                            17
18
             THE WITNESS: And they asked us for
                                                            18
                                                                    have here is, both the FDA and Dr. Bailey noted
19
       follow-up information, which -- which we provided.
                                                            19
                                                                    that the -- that the standards that were adopted
20
       BY MR. TISI:
                                                            20
                                                                    in the 1970s were then decades old, correct?
21
                                                            21
          Q Now, one of the things we learned in
                                                                          MR. LOCKE: Objection.
22
       this litigation is that these folks down here, the
                                                            22
                                                                          THE WITNESS: Noted where? At the
23
       J&J and Imerys, had talc samples available to them
                                                            23
                                                                    meeting?
24
       for decades.
                                                            24
                                                                    BY MR. TISI:
25
             MR. TISI: Objection.
                                                            25
                                                                       Q At the meeting. It says here -- if you
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44 (Pages 548 to 551)

Page 552 Page 554 1 go back to the meeting notes, it says --1 A -- and is used by USP. 2 MR. LOCKE: Can you tell us which 2 Q Did you go back and see whether or not 3 3 exhibit you're referring to? there are other methods that would guarantee that 4 MR. TISI: Exhibit No. 55. 4 asbestos had been eliminated -- well, let me 5 5 BY MR. TISI: rephrase the question for you. 6 6 Is -- is it a -- would you agree with me Q It says -- if you go to page 2, it says: 7 "Dr. Bailey mentioned that the Council published 7 that the goal here is to eliminate asbestos from 8 specifications for talc as well as analytical 8 cosmetic talc? You don't want any asbestos in methodology for asbestos. These are the ones most 9 9 cosmetic talc. Would you agree with that? 10 often cited for the raw material. He mentioned 10 A That's the ideal. 11 these were developed almost 20 -- 20 years ago, 11 Q That's the ideal. and that they would need to be checked for 12 12 Particularly since this is a product 13 verifications." 13 that honestly there are other -- it's a cosmetic, 14 and there are other alternatives out there, right? Do you see that? 14 15 MR. LOCKE: Objection. A Yes. 15 16 Q Okay. And so one of the things that the 16 THE WITNESS: You don't need talc to 17 FDA and -- and the PCPC were talking about is, are 17 live, yes. 18 our specifications for testing tale, are they 18 BY MR. TISI: 19 outdated? Are they as stringent as they ought to 19 Q Right. And to the extent you do need it 20 be? Correct? 20 to live, there's corn starch, right? 21 MR. LOCKE: Object -- objection. 21 MR. LOCKE: Objection. 22 THE WITNESS: There's alternatives, yes. THE WITNESS: That's what he's talking 22 23 about here, yes, but he's certainly saying that we 23 BY MR. TISI: 24 welcome FDA's --24 Q Right. And so the question is, in light 25 BY MR. TISI: 25 of that, you don't want any asbestos, none, zero. Page 553 Page 555 1 O Of course. 1 You want it eliminated. True? A -- to weigh in, and --2 2 A You want it to be very low. My 3 Q Right. But the -- but the question is, 3 understanding is the methodologies that are used, 4 when these specifications were -- were developed 4 it's actually gotten lower in detection limits, 5 in the 1970s, the epidemiology studies hadn't come 5 and we are using what -- again, the equivalent of 6 out yet, right? They didn't come out until 1982. 6 a USP method. 7 You made it clear that it was the early 1980s. 7 Q Okay. All right. Now, let's talk about 8 8 A That's true, yes. other aspects of this report, if we could. 9 Q Okay. And so now you had a new 9 First of all, can you -- I asked you 10 potential risk that was really raised by the 10 whether or not -- on the asbestos issue, whether 11 epidemiology studies, and one of the questions 11 or not the company had ever gone back and -- the 12 that you had to answer is, are those a 12 companies that were the primary people here had 13 biologically plausible mechanism, right? 13 ever gone back and actually tested samples that it 14 MR. LOCKE: Objection. 14 had in its possession that went back decades, and 15 THE WITNESS: Yes. 15 you indicated you didn't even know they had them, 16 BY MR. TISI: 16 right? 17 17 Q Okay. And in light of that, did you A Right. 18 ever go back and say, Do we need to tighten up our 18 MR. LOCKE: Objection. 19 standards and to use a different measurement that 19 BY MR. TISI: 20 20 would make sure that we had, using your terms in Q Were you able to produce to the FDA any 21 21 here, "eliminated asbestos"? testing records, any -- any literature, any 22 A I guess I'm just aware that basically 22 outside audit, anything, that went back and looked 23 the methods -- methodology used is still what is 23 at talc being tested to demonstrate the 24 24 used today -truthfulness of what Drs. Huncharek and Muscat 25 Q Right. 25 assumed, that asbestos had been eliminated? Or

45 (Pages 552 to 555)

Page 556 Page 558 1 did you just make the statement? 1 cetera. I mean, the --2 A I mean there was a great deal of testing 2 BY MR. TISI: 3 that went on in the early '70s --3 Q Well, the FDA on the translocation issue 4 Q Right. 4 said that that's definitely biologically 5 5 A -- to show it was not detectable, and plausible. 6 that's what the specification says. 6 A They did say that. 7 Q Got you. From the 1970s. Now you're 7 Q Okay. So let's --8 meeting with them in -- in May of 2008. They're 8 A I'm not sure what their basis was asking you about asbestos. Right? So now we're 9 9 because they didn't reference, but they did say 10 the '70s, '80s, '90s, 2000s, it's almost 30 years. 10 that. Between the 1970s and the 2000s, did you 11 11 Q Well, but you didn't reference proof that there was -- okay. Let's -- so let's be fair 12 come forward, either on your behalf or did any of 12 13 these companies come forward and say, Look, we're 13 here. Okay. 14 going to show you proof that our talc from the 14 You say the FDA didn't -- didn't 15 1970s forward did not have asbestos in it, or was 15 reference the support for a translocation. Fine. 16 that statement just made? 16 What is your reference that in the 17 A I think it -- the basis of the statement 17 1980s, 1990s and 2000s, there was no contaminants 18 was, again, the work that had done -- been done in 18 in talc, talcum powder products, that were 19 the '70s to set up the specification. It was the potentially biologically plausible mechanisms that 19 20 discussions that followed with FDA to talk -- to 20 would explain what we all agree is a trend towards 21 answer the questions about sourcing and testing. 21 an increased risk seen in the epidemiology 22 22 studies? Q Agreed. 23 A I think if you're taking "elimination" 23 MR. LOCKE: Objection. 24 to mean a literal zero, I can't think of any 24 THE WITNESS: I mean there was no 25 contaminant that anybody can say is a literal 25 evidence for talc itself. As I say, perfume Page 557 Page 559 1 1 fragrance is not regarded -zero. 2 Q So do you know -- did you take into 2 BY MR. TISI: 3 account whether or not talcum -- talcum powder 3 Q You don't look at it. 4 products have fragrances, right? 4 A -- as a carcinogen. 5 5 Q You don't look at it. Did you? A Yes. 6 Q Did you look at the fragrances in there б A We --7 to see whether that provided a biologically 7 O Has there been a lot of discussion 8 plausible mechanism? 8 about -- let me --9 MR. LOCKE: When you say "look" -- "did 9 A Fragrance in general. I mean it's used 10 you look," are you referring -in body lotion, it's used in -- as fragrance. 10 11 MR. TISI: PCPC. It's used in --11 12 BY MR. TISI: 12 Q Right, but it doesn't -- it doesn't --13 Q Did PCPC, when it provided this report 13 A It's not considered carcinogenic. 14 to the -- to the FDA talking about Q -- it doesn't -- but is body lotion, 14 biologic plausibility, there's no way this 15 15 does that come in contact with your ovaries, happens, right? When you said that to the FDA, 16 16 typically? Are there any epidemiology -- are okay, did you consider whether or not what was in there any epidemiologies that's --17 17 18 the bottle contained other things that might A The components of fragrance are not 18 provide that mechanism? 19 19 regarded as --20 Q Did you look? MR. LOCKE: Objection. 20 21 THE WITNESS: I mean, I -- I think when 21 A Look at? 22 you're talking about fragrance, which we -- is 22 Q Every component that was in the bottle, did you look at each one of them and see whether 23 part of a lot of products, I mean, we do not think 23 24 of fragrances as being carcinogenic, not to or not there was things that could be in that 24 25 mention the whole thing about translocation, et 25 bottle that provided a biologically plausible --

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Page 560 Page 562 1 or did you look solely at pure talc? 1 A If somebody wanted to address our 2 A I guess the -- the main thing I think of 2 arguments and disagree with them, they could do 3 3 is fragrance, and certainly we've been concerned 4 with fragrance and have an understanding of what 4 Q Okay. So let's talk about -- let's just 5 5 fragrance materials are, and -go here, because I think this will be -- and then 6 Q Do you know whether or not -- did -- did 6 we'll just break for lunch. I think it's lunch. 7 you ask them whether it contains nickel and 7 Yeah, we'll break for lunch. 8 8 chromium and silica or any of those other --If you go to page -- if you go to 9 talcum powder comes from the ground, right? 9 page 21 of the Introduction. 10 10 A Yes. A This is 21 --11 Q Okay. And those are things that are 11 Q I'm sorry, 24 of 39 if you're looking at not -- that are not desirable in talc either, 12 12 the --13 right? 13 A 24 of 39, okay. 14 14 Q So at the very last, it talks about A Correct. experimental studies and clinical trials. Do you 15 Q Okay. So my question is, your whole 15 16 premise for this opposition for Citizen's 16 see that? 17 Petition -- Dr. Epstein wanted a warning on talcum 17 It says: "In the contest of human 18 powder products, which is everything in the 18 studies, experimental design has come to represent 19 bottle. Right? 19 the gold standard of cause and effect relationship 20 A Yes. 20 as the randomized clinical trial." 21 Q Your response focused on talc. Correct? 21 22 MR. LOCKE: Objection. 22 Q Okay. First of all, would you agree THE WITNESS: Which makes up the vast with me -- I mean, you've done this for a long 23 23 24 majority of the product. 24 time -- you would agree with me that it would be 25 BY MR. TISI: 25 both unfeasible and unethical to conduct a Page 561 Page 563 1 Q The vast majority of the product but not 1 clinical trial where the hypothesis was, Let's 2 all of the product. Correct? 2 give people talcum powder products and see whether 3 A I mean, we -- we have other lines of 3 it causes ovarian cancer. 4 evidence, and our -- and -- and the arguments that 4 A Right. That's not how you do studies. 5 we make are -- I mean, we're not alone in this. 5 Q You can't do it. 6 We're consistent that there is --6 A Right. 7 Q I understand. But there are other 7 Q So you can't -- so a clinical trial, if 8 8 anyone were to kind of march on into court and people who think differently than you, right? You 9 say you're not alone. There are other scientists 9 say, You know, there were no clinical trials, you 10 who look at the evidence and think differently 10 would expect to see clinical trials on this? 11 11 A Correct. That's not how it's done. than you. 12 A As -- as we've discussed. 12 Q Right. So the next question is they have to rely on epidemiology research. Do you see 13 Q And they weren't in the room when you 13 14 were discussing with the FDA, were they? 14 that? 15 A But, again, I -- I don't think we were 15 A Yes. 16 even having --16 Q Okay. And they lay out a methodology here. It says: "An epidemiologist must observe 17 Q No, they were -- they were not in the 17 observational methods to cause and effect 18 18 room. MR. LOCKE: Let her finish the question. 19 relationship that preclude direct intervention on 19 20 20 manipulation of study subjects." BY MR. TISI: 21 21 Q They were not -- only you were in the That's experiments, right? 22 room. And --22 A Yes. 23 A But we submitted this -- these are our 23 Q All right. "Because of that fact, 24 24 criteria for establishing cause and effect arguments; they get posted on the website. 25 Q Okay. relationship are inherently different when

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	Page 564		Page 566
1	utilizing epidemiologic methods versus	1	A I that's reasonable.
2	experimental ones."	2	Q Okay. And that's not unusual in
3	Do you see that?	3	science. Right?
4	A Yes.	4	A Correct. Scientists disagree.
5	Q Okay. And so what they're saying is,	5	Q I mean, for years there was a debate
6	Look, you can't do a clinical trial because it's	6	about whether cigarette smoking causes cancer,
7	unworkable, unethical. You just can't do it. So	7	right?
8	you got to do it a different way.	8	MR. LOCKE: Objection. Beyond the
9	A Yes.	9	scope.
10	Q Okay. And one of the ways that they do	10	THE WITNESS: Yeah, before my time. I
11	it, they describe a a system or framework,	11	think I've always known it, but yes.
12	okay, and the framework is what we've called the	12	BY MR. TISI:
13	Bradford Hill criteria, and you've seen that	13	Q Right. But you know that there was a
14	before?	14	debate for decades on that question.
15	A Yes.	15	MR. LOCKE: Same objection.
16		16	=
	•		THE WITNESS: I really don't. So
17	you're familiar with what that is?	17	BY MR. TISI:
18	A Yes.	18	Q You don't know that?
19	Q Okay. And just to be clear,	19	A No.
20	Dr. Huncharek and Muscat make it clear, but I want	20	Q You must be much younger than me.
21	to make clear that from PCPC agrees with it as	21	But you do know that that it is not
22	well, these are criteria that are not really	22	unusual for scientists to look at a question,
23	criteria. They're they're considerations.	23	apply these factors, and come out with different
24	A They're right. Guidelines, I guess,	24	conclusions, correct?
25	or right.	25	A Yes.
	Page 565		Page 567
1	Q Right. They're not things where you	1	Q And so these are not criteria so much,
2	kind of it's not like a menu where you check	2	these Hill factors, as they are a framework of
3	off, Okay, we got this one, we got that one, we	3	considerations.
4	got this one, right?	4	MR. LOCKE: Objection. Beyond the
5	A You use it for overall, right,	5	scope.
6	assessment.	6	BY MR. TISI:
7	Q Right. And they make that point. They	7	Q True?
8	say: "The Hill criteria, as they've become known,	8	A "Framework" is what it says here.
9	are not simply a checklist of requirements that	9	Q And you agree with that?
10	must be met in order to determine a cause and	10	A Yes.
11		l	
	effect relationship."	11	Q They also say something here that I
12	effect relationship."  And that's true, right?	11	Q They also say something here that I that I want to see whether you agree with and you
12	And that's true, right?	12	that I want to see whether you agree with and you
12 13	And that's true, right?  A Yes.	12 13	that I want to see whether you agree with and you agreed with at the time.
12 13 14	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think	12 13 14	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the
12 13 14 15	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are	12 13 14 15	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go
12 13 14 15 16	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?	12 13 14 15 16	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.
12 13 14 15 16 17	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking	12 13 14 15 16 17	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility
12 13 14 15 16 17 18	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking about before that I think is really important to	12 13 14 15 16 17 18	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility that perineal talc exposure could be associated with the development of ovarian cancer was
12 13 14 15 16 17 18 19	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking about before that I think is really important to kind of why this has been a debate is because	12 13 14 15 16 17 18	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility that perineal talc exposure could be associated with the development of ovarian cancer was initially derived from a case controlled study
12 13 14 15 16 17 18 19 20	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking about before that I think is really important to kind of why this has been a debate is because different scientists looking at the evidence have	12 13 14 15 16 17 18 19 20	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility that perineal talc exposure could be associated with the development of ovarian cancer was initially derived from a case controlled study published in 1982."
12 13 14 15 16 17 18 19 20 21 22	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking about before that I think is really important to kind of why this has been a debate is because different scientists looking at the evidence have come to different conclusions about these	12 13 14 15 16 17 18 19 20 21 22	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility that perineal talc exposure could be associated with the development of ovarian cancer was initially derived from a case controlled study
12 13 14 15 16 17 18 19 20 21 22 23	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking about before that I think is really important to kind of why this has been a debate is because different scientists looking at the evidence have come to different conclusions about these different factors.	12 13 14 15 16 17 18 19 20 21 22 23	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility that perineal talc exposure could be associated with the development of ovarian cancer was initially derived from a case controlled study published in 1982."  Do you see that?  A Yes.
12 13 14 15 16 17 18 19 20 21 22	And that's true, right?  A Yes.  Q Okay. And so these factors, and I think they have nine of them here, are factors that are considered, correct?  A Yes.  Q And and kind of what we were talking about before that I think is really important to kind of why this has been a debate is because different scientists looking at the evidence have come to different conclusions about these	12 13 14 15 16 17 18 19 20 21 22	that I want to see whether you agree with and you agreed with at the time.  On page 26 of 29 well, one of the things they say here is actually, let's go back.  It says: "Overview. The possibility that perineal talc exposure could be associated with the development of ovarian cancer was initially derived from a case controlled study published in 1982."  Do you see that?

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Page 568 Page 570 1 Q "Since that time a number of additional 1 Q Do you agree with it? 2 reports have addressed this question with most 2 MR. LOCKE: Objection. Beyond the 3 showing odds ratio between 1.0 and 2.0." Correct? 3 scope. 4 A Yes. 4 BY MR. TISI: 5 5 Q Okay. That's -- that's between -- if we Q On behalf of PCPC, is that something 6 were to -- and for jurors who don't understand 6 that PCPC agreed with when they sent this to the 7 odds ratios, that's basically showing anything 7 8 from a 1 percent increase to 100 percent increase. 8 MR. LOCKE: Objection. Beyond the 9 A Correct. 9 scope. 10 Q Okay. 2.0 would be a doubling of the 10 THE WITNESS: We -- yes. 11 risk. 11 BY MR. TISI: 12 12 Q Thank you. A Correct. Did PC -- they note down here that 13 Q And that's what they call -- they call 13 14 this a weak effect. Correct? obviously -- actually, let's skip that. 14 15 MR. LOCKE: Is this a good time for a 15 A Yes. 16 Q So just using the nomenclature that 16 lunch break? 17 Dr. Muscat and Huncharek used, they would 17 MR. TISI: Yeah, it's a good time to 18 characterize something less than a hundred percent 18 break. 19 doubling of the risk as being weak. THE VIDEOGRAPHER: The time is 19 20 A Per an epidemiology study, yes. 20 12:32 p.m., and we're going off the record. 21 Q Right. But in practical reality, if you 21 (Lunch recess.) THE VIDEOGRAPHER: The time is 1:12 22 find something that doubles your risk, that is a 22 clinically -- if it is a true cause, that's p.m., and we are back on the record. 23 23 clinically significant, correct? 24 24 BY MR. TISI: 25 A If it --25 Q Dr. Loretz, we were talking about the Page 569 Page 571 MR. LOCKE: Objection. 1 1 purity of talcum powder products that -- that's in 2 THE WITNESS: -- is a true cause. 2 the bottle, and distinguishing it from talc in the 3 MR. LOCKE: Beyond the scope. 3 mine and et cetera, and before we took a break. BY MR. LOCKE: 4 4 Do you remember that --5 5 Q If it is a true cause. All right. A Yes. 6 So now the question is, if you go to 6 Q -- session? 7 page 23, they make the point, and they go out of 7 I have a couple more questions about 8 their way to make it, actually, because they say: 8 that and the document, but before I do, the focus 9 "It is important to point out that although an 9 of the PCPC response was to focus on the 10 association is weak" --10 carcinogenic -- carcinogenic -- I'm sorry, let me 11 MR. LOCKE: Just wait -- wait one 11 say it again. 12 second. You're referring to 23 at the top --12 The focus of the biologic plausibility 13 MR. TISI: I'm sorry. 26 of 39, aspect of Dr. Muscat and Huncharek's response was 13 14 14 focused on two things. Number one, that talcum correct. 15 BY MR. TISI: 15 powder products had been asbestos-free since 16 Q "It is important" -- it says on the 16 1970s, it had been eliminated. first full paragraph: "It is important to point 17 17 Do you remember that? 18 out that although an association is weak" -- and 18 A Yes. 19 as they define "weak," that can include a doubling 19 Q Okay. Number two is that pure talc did 20 of the risk, right? 20 not -- there was no evidence that pure talc was 21 21 A Up to. a -- had a mechanism that would lend itself to the 22 Q Right. 22 suggestion that it was a cause of ovarian cancer. 23 -- "this does not rule out a causal 23 Correct? 24 connection." Do you agree with that? 24 A Right. 25 A That's what it says. 25 Q Right. So you were looking at asbestos,

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Page 572 Page 574 1 not there anymore; and talc, not a problem. 1 attention that there are potentially other 2 Right? 2 components of talcum powder products, constituents 3 3 A Yes. of talcum powder products, that need to be 4 Q Okay. So -- but -- and we talked about 4 considered when addressing the question as to 5 5 the question about whether or not talc really was whether or not talcum powder products are a 6 asbestos-free before the -- the break, and I'm not 6 potential cause of ovarian cancer? 7 7 going to go back into that again, but that was an A Are you talking about constituent 8 8 area of concern from the FDA's perspective, and ingredients or are you talking about constituent 9 9 they raised it at the May meeting, May 2009. impurities? 10 10 A And -- and I'm sure -- we responded by Q Anything. Anything in the --A I mean --11 letting them know that the testing that had been 11 12 done and continued to be done. 12 Q You know, honestly, and I'm trying to be 13 Q Correct. Using --13 -- I'm trying to be as expansive as I can in this 14 question. A And their own testing as well that they 14 What I'm saying is, if I go to Walmart 15 did. 15 16 Q Using the 12 -- we'll talk about that in 16 and pull a bottle of talcum powder, Johnson's Baby 17 a moment, but using the 20-year-old standards that 17 Powder off the shelf, whether they're impurities 18 Dr. Bailey mentioned that they would be willing to 18 or whether they're intended ingredients or 19 19 whatever, there are other constituents in there update. 20 A Which --20 that have to be considered in the algorithm of 21 MR. LOCKE: Objection. 21 whether or not talcum powder products cause 22 22 ovarian cancer. True? BY MR. TISI: 23 23 Q Correct? A There are impurities that are covered by 24 A Which they -- which, again, are not 24 the specification, for example. 25 substantially different from what is used today 25 Q Right. But -- but so my -- my question, Page 573 Page 575 1 1 and I'm probably being inartful, so let me see if by, for example, USP. 2 Q Okay. So we discussed asbestos and 2 I can phrase it. 3 talc, and I started getting into the question, but 3 We've previously discussed talcum powder 4 you know what's in the bottle, it's not only 4 products as kind of this two-dimensional thing, 5 asbestos and talc. Remember we started that 5 either it has asbestos or it doesn't have 6 discussion before the break. 6 asbestos. Right? So --7 7 A Yes. A Okay. 8 8 Q Okay. And in fact, that had been Q So I'm -- I'm kind of moving off that 9 brought to your attention long before this 9 because it's not that simple, is it? 10 petition was filed that talcum powder products may 10 MR. LOCKE: Objection. 11 contain things that might or might not be 11 BY MR. TISI: 12 carcinogens. 12 Q The question about whether or not there 13 A Okay. 13 is a biologically plausible mechanism by -- that 14 Q Well, is that true? 14 would explain the epidemiology studies which 15 A I'm not sure what you're referring to. 15 showed, as Dr. Huncharek and Muscat point --16 Q Well, I'm asking you that before I --16 pointed out, a risk between one and -- you know, and a hundred percent, right? One to two, what 17 A I mean in the specific --17 Q -- show you a document --18 you say is called mild. The question should be 18 19 looked at comprehensively as to what is in the 19 A In the specification we have some limits 20 set for a few other possible contaminants. 20 bottle. 21 21 Q Well, had it ever been brought to your MR. LOCKE: Objection. 22 attention that talcum -- you mentioned -- we 22 BY MR. TISI: 23 talked about fragrances, we talked about other 23 O Right? A Yes, I'm not aware of anything that --24 24 things. 25 Had it ever been brought to your 25 Q Well, did you look? I mean, the

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	Page 576		Page 578
1	question is this this report that was sent to	1	throw it at you.
2	the FDA takes a very elemental view of the	2	BY MR. TISI:
3	question. Prior to 1970, there was potential	3	Q I'm really going to only ask you about
4	contamination with asbestos. It went out, and	4	the first page.
5	what's left is talc.	5	A Mm-hmm.
6	MR. LOCKE: Objection.	6	Q So just for the record, what this is,
7	BY MR. TISI:	7	this is a document from IMA Europe. What is IMA?
8	Q And talc doesn't cause cancer. That was	8	A Industrial Minerals Association.
9	the essence of their argument, correct?	9	Q So it's another trade group like the
10	MR. LOCKE: Objection.	10	PCPC?
11	THE WITNESS: Well, no, I think there's	11	A Correct.
12	more in their arguments I mean	12	Q Okay. It represents talc
13	BY MR. TISI:	13	A Mineral manufacturers, and talc is a
14	Q On the biologic plausibility issue, I	14	subset of that.
15	mean, they talked about dose-response and all that	15	Q Okay. And it's to Dr. Muscat, correct?
16	stuff. But I'm talking about on the biologic	16	A Yes.
17	plausibility, on the question of whether there is	17	Q Okay. Is this the same Dr. Muscat who
18		18	wrote the report a couple of years later for you?
	a an explanation that makes sense as to why	19	
19	there's this persistent increased risk, they	20	
20	looked basically at asbestos in talc.		Q Robert Glenn at Crowell & Moring. R.
21	MR. LOCKE: Objection.	21	Glenn.
22	THE WITNESS: Yeah, I'm not sure what	22	A I'm sure it is there. I don't see it.
23	what other what else you wanted to be them	23	Q It's right after Joshua Muscat.
24	to address.	24	A Yep. Yes.
25	BY MR. TISI:	25	Q R. Glenn, Crowell & Moring, that's the
	Page 577		Page 579
1	Q Well, are there other things, either	1	lawyers for
2	contaminants or intended ingredients, that should	2	A Yes.
3	be factored into the equation that were not	3	Q they represent the lawyers for for
4	addressed by their had let me rephrase the	4	Imerys.
5	question. And I'm sorry, I'm not being artful	5	Linda Loretz is you?
6	here.	6	A Yes.
7	Are there other constituents within	7	Q Eric Turner, which is Luzenac, which is
8	cosmetic talc that should be should have been	8	Imerys?
9	considered on this biologically plausible	9	A Yes.
10	mechanism issue that were not?	10	Q Jocelyn Ferret, which is Luzenac
11	A I I no, I'm not aware of	11	A Yes.
12	Q Okay. But no other constituents were in	12	Q Imerys?
13	fact considered, right?	13	So and cc'd was Steve Mann for
14	A There's a specification that covers	14	from J&J. You see that?
15	some.	15	A Yes.
16	Q Okay. Were you ever made aware prior to	16	Q And it's entitled "IARC, Dr. Huncharek
17	this time that there were other potential	17	Comment." Do you see that?
18	constituents that had been classified as a	18	A Yes.
19	carcinogen other than asbestos?	19	Q Okay. And this is February 13th, 2006.
-			This was during the IADC proceedings?
20	A No.	20	This was during the IARC proceedings?
	<ul><li>A No.</li><li>Q I'm going to show you what I would like</li></ul>	21	A Okay. Yes.
20		l .	
20 21	Q I'm going to show you what I would like	21	A Okay. Yes.
20 21 22	Q I'm going to show you what I would like to have marked as Exhibit No. 59.	21 22	A Okay. Yes. Q Is that right?

51 (Pages 576 to 579)

Page 580 Page 582 1 representative at IARC at the time. 1 When you filed your response to the 2 A Correct. 2 Citizen's Petition, and addressed the issue of 3 Q Yes? 3 biologically plausible mechanisms, did you ask 4 A Yes. 4 Dr. Muscat and Huncharek to look at each of the 5 5 Q And it says: "What should be constituents in cosmetic talc sold in talcum б acknowledged is the difference between cosmetic 6 powder products and see whether or not they 7 talc grade, i.e., grade of talc, pure and 7 individually or collectively might explain the 8 extremely white, sold by talc producers at the 8 increased risk? 9 gate of the mine" -- right? 9 A I think the other ingredients that are 10 A Yes. 10 used in talc are not carcinogenic. 11 Q -- "and cosmetic baby or body talc 11 Q Well, did you -- what are the other talcs -- did you ask J&J to provide you with a 12 powder, i.e., loose powder manufactured by 12 13 cosmetic manufacturers containing talc or corn 13 list of -- list of products using talc? 14 starch, and also in the case of other minerals, A List of ingredients used in talc? 14 15 kaolin, Ti02, and all case additives such as 15 Q List of ingredients of talc. 16 perfumes and biocides, hexachlorophene in the 16 A No. 17 past, a Category 3 IARC carcinogen" -- I won't 17 Q Okay. So how do you know that none of 18 even pronounce that -- imidazolidinyl urea" -- I 18 them are carcinogenic? 19 don't know how to pronounce that -- "triclosan, et A We don't use carcinogens in cosmetics. 19 20 cetera. See documents sent by Jocelyn Ferret this 20 Q You don't know what was in the talc that 21 morning." 21 you were talking about with -- with the FDA, do 22 22 A Uh-huh. you? 2.3 Q Okay. And the point that's being made 23 MR. LOCKE: Objection. 24 here -- and, first of all, you got this. The 24 BY MR. TISI: 25 point that's being made here is one of the things 25 Q I mean -- I understand that Page 581 Page 583 1 that really ought to be considered when you're 1 aspirationally you don't want to have 2 talking about talcum powder products and the risk 2 carcinogen -- carcinogens in the talc that you 3 of ovarian cancer, you need to think about not 3 sell to women who may use them to dust themselves. 4 I -- I understand that that might be an 4 only what comes out of the mine but what's in the 5 5 bottle. aspiration. 6 MR. LOCKE: Objection. 6 But in light of the fact that this issue 7 BY MR. TISI: 7 had been pending for decades, and now was firmly 8 8 Q Right? before the FDA in the Citizen's Petition, do you 9 9 think that it might have been prudent to identify, A Okay. 10 Q Well, I mean, I'm asking you whether you 10 just as was identified in this document I showed 11 11 agree with that or not. you, Exhibit No. 59, what all the constituents are 12 A I can agree with that without thinking 12 in order to do a searching analysis of whether or 13 that this explains anything. 13 not there was something in the talc that might be 14 Q Okay. 14 responsible for this increased risk? A Yes. 15 15 MR. LOCKE: Objection. 16 Q Okay. 16 THE WITNESS: I mean, I guess, you know, A I mean you think about -- when you think 17 I can look at this, and I recognize these 17 about safety of a product -ingredients, and --18 18 19 Q Well, I'll take it and I'll put it aside 19 BY MR. TISI: 20 20 Q Well, these are some of them and there then. 21 21 A No, I'm just saying when you think about may be others. I mean you -- what about did you 22 safety of a product, you think about everything in 22 know how much silica was in the -- if any, was in 23 the product. So... 23 the talcum? 24 Q Well, that's right. And -- and that's 24 A There's specifications. 25 kind of where I'm going here. 25 Q I understand the specifications. Apart

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Page 584 Page 586 1 from the specifications, do you know how much 1 constituents, right? 2 silica there was? 2 A I believe that's true. 3 A No. 3 Q And they did not talk about any of the 4 4 fragrance or any of the other issues that are in Q Do you know how much magnesium there 5 was? 5 there, correct? 6 A For the same reason. A I'm not sure that's regarded as a 6 7 carcinogen. 7 Q Okay. Talk about cobalt? 8 Q What about nickel? 8 A No. 9 A I know there was at one point, there was 9 O Arsenic? 10 a report and it was our understanding, because 10 There is a specification for arsenic. Α 11 this is what we were told, that it was bound up in 11 Q Right. But saying something has a specification does not mean that it's absent, 12 the talc and not free nickel. 12 13 Q Well, who told you that? 13 correct? 14 A I think it was J&J. 14 A Right. I mean there's a specification 15 Q Okay. What about -- what about set, I believe it's 3 parts -- I believe it's 3 15 16 silica -- is nickel a carcinogen? parts per billion. 16 17 A I don't believe it's recognized as an 17 Q Right. 18 ovarian carcinogen, but I'm -- I'm not an expert A So it could be up to that. 18 19 on nickel cariogenicity. Q So when you say something meets 19 Q Okay. If there -- if there was nickel, 20 20 specifications, the specifications are only as 21 it would be something that you would want to look 21 good as the sensitivity and specificity of the 22 22 test that's being used. at, right? A I think it depends. 23 23 A Well, the specifications are designed to 24 MR. LOCKE: Objection. 24 set a level that would be acceptable, i.e., safe, 25 THE WITNESS: I mean --25 and the method that goes with that should be Page 585 Page 587 1 1 designed to --BY MR. TISI: 2 Q Well, my -- my larger point here, 2 Q And did --3 Doctor -- and, you know, I don't want to belabor 3 A -- test at that level. Q And did you -- because you were involved 4 the issue -- is when you responded to the FDA, the 4 5 with working with those standards, right, and Citizen's Petition, there is nothing in this 5 6 response that addresses the potential of any 6 helping develop those standards, right? 7 contaminants in the product, even ones that meet 7 A Oh, no, that was before my time. 8 8 Q Okay. Well, I didn't mean you. I meant specifications. Is there? 9 MR. LOCKE: Are you referring solely to 9 PCPC. 10 biological plausibility? 10 A PCPC, yeah, absolutely. Q I was putting the PCPC hat on. 11 BY MR. TISI: 11 12 Q On the biologic plausibility issue, 12 A Okay. Sorry. Got it. Q All of those specifications were 13 there's no discussion at all, nickel, chromium, 13 14 silica, asbestos to the extent that's in it since 14 developed before the epidemiological studies on 15 the 1970s, there's no discussion of that, is 15 ovarian cancer, true? 16 there? 16 A Developed but then updated, post. Q I guess my question is, did any of 17 A Because those weren't recognized as 17 18 those -- were any of those specifications, to your being risks. Just as I state some of these are 18 19 knowledge, analyzed by PCPC in the context of not --19 20 Q Okay. And that's -- it was not part of 20 looking for biologically plausible mechanisms for 21 Dr. Huncharek and -- and Muscat's analysis to the 21 ovarian cancer? 22 22 A I guess I'd go back to, I can see a FDA, right? 23 MR. LOCKE: Objection. 23 listing here that it just --24 24 Q I didn't ask you that question. You BY MR. TISI: 25 Q They did not mention those other 25 told me that you could answer the question without

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	Page 588		Page 590
1	looking at that document.	1	quite here yet.
2	A Okay.	2	A Okay.
3	Q So I'm not looking at that document.	3	Q So we'll put it up on the screen and
4	A Okay.	4	have it.
5	Q My question is, did you did PCPC in	5	Dr. Epstein had previously filed a
6	the 2000s, while these epidemiological studies	6	Citizen's Petition before the FDA in the 1990s on
7	were being published, analyze the specifications	7	this issue, correct?
8	for the elimination of these other constituents in	8	A Yes.
9	light of those epidemiology epidemiological	9	Q And at that time who did that petition
10	studies?	10	go to, do you know?
11	A We no, we were not aware of other	11	A John Bailey, I believe.
12	contaminants and/or ingredients that seemed to	12	Q While he was at the FDA?
13	offer a biological plausible reason for the cause	13	A I believe so, yes.
14	of ovarian cancer.	14	Q And did the FDA ever respond to that?
15	Q Well, cobalt might, right? Did you look	15	A Yes, they rejected that petition.
16	at the cobalt cobalt standards in connection	16	Q Well, didn't they didn't Dr. Bailey
17	with ovarian cancer your standards?	17	write a letter to Mr to Dr. Epstein that
18	A I was	18	said and we'll bring it up here.
19	MR. LOCKE: Objection.	19	MR. TISI: Can we bring it up, please?
20	THE WITNESS: I would say we had no	20	MR. GOLOMB: I don't
21	information that the cobalt contamination was a	21	MR. TISI: Well, we'll attach it as an
22	problem, and I'm not aware that cobalt has been	22	exhibit. No, that's it. Oh, is that it? No
23	implicated in ovarian cancer, although	23	yeah.
24	BY MR. TISI:	24	BY MR. TISI:
25	Q Arsenic.	25	Q The last it's dated July 21st, 1995,
	Daga E00		
	Page 589		Page 591
1	A I'm not an expert.	1	and that's Dr. Bailey who wrote that
1 2		1 2	
	A I'm not an expert.		and that's Dr. Bailey who wrote that MR. TISI: Can you make that BY MR. TISI:
2	<ul> <li>A I'm not an expert.</li> <li>Q Arsenic.</li> <li>A There's a specification for that.</li> <li>Q Did you analyze that specification in</li> </ul>	2	and that's Dr. Bailey who wrote that MR. TISI: Can you make that
2 3 4 5	<ul> <li>A I'm not an expert.</li> <li>Q Arsenic.</li> <li>A There's a specification for that.</li> <li>Q Did you analyze that specification in light of the the reported epidemiology results</li> </ul>	2 3	and that's Dr. Bailey who wrote that MR. TISI: Can you make that BY MR. TISI:
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2 3 4 5	<ul> <li>A I'm not an expert.</li> <li>Q Arsenic.</li> <li>A There's a specification for that.</li> <li>Q Did you analyze that specification in light of the the reported epidemiology results of ovarian cancer in talc?</li> <li>A I feel pretty comfortable saying that</li> </ul>	2 3 4 5	and that's Dr. Bailey who wrote that MR. TISI: Can you make that BY MR. TISI: Q and his response was MR. TISI: Go the second paragraph, please. MR. GOLOMB: Second one?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A I'm not an expert. Q Arsenic. A There's a specification for that. Q Did you analyze that specification in light of the the reported epidemiology results of ovarian cancer in talc? A I feel pretty comfortable saying that the specification would would be okay, and I'm not aware that arsenic has been implicated as an ovarian carcinogen. Q It didn't are they carcinogens? Would it be something that would have been to be looked at in light of the epidemiological studies? MR. LOCKE: Objection. THE WITNESS: I'm not sure that offers a biologically plausible explanation. BY MR. TISI: Q So the fact that something okay. All right. One other question. (Counsel conferring.) Q All right. Let's go to Exhibit No okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	and that's Dr. Bailey who wrote that MR. TISI: Can you make that BY MR. TISI: Q and his response was MR. TISI: Go the second paragraph, please. MR. GOLOMB: Second one? MR. TISI: Mm-hmm. BY MR. TISI: Q "The purpose of this is to advise you, in accordance with 21 CFR 10.30(e)(2), that we have not been able to reach a decision on your petition within the first 180 days of the filing of the petition because of limited availability of resources and other agency priorities." Is that accurate? A Yes. Q Okay. And this Citizen's Petition, the one we've been talking about all day, wasn't responded to for five years. Correct? A Yes. Q And that's the same division that

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Page 592 Page 594 1 that is -- I think it's pretty typical for 1 questions. 2 petitions that they, I believe, have some 2 A Okay. 3 3 Q The first question is going to be obligation to respond, but that response can be to 4 say that we're not -- we're not done yet. 4 communications with the FDA on talc and ovarian 5 5 (Exhibit No. 60 was subsequently cancer association or risk. 6 marked for identification.) 6 And the second question is going to be 7 7 on specifications for talc, and particularly with BY MR. TISI: 8 8 regard to asbestos. Okay? Q Okay. I'm going to mark it as 9 9 Exhibit No. 60 when we get it. So the first question, in 2010, do you 10 recall any question or any communications with FDA 10 So let me ask you this: I'm going to go 11 through each year, and I'm going to ask you, you 11 regarding the issue of ovarian cancer and talc? responded to the FDA questions that they asked 12 A I don't recall any, no. 12 13 you, correct, at this May 9th --13 Q Any communications with the FDA on any 14 specifications for issues relating to asbestos or A Yes. 14 15 15 levels of asbestos in talc? Q -- meeting? 16 Did PCPC in 2009, other than this 16 A Not that I recall. 17 meeting, have any communications directly or 17 Q Okay. 2011, same two questions. If you 18 indirectly with FDA relating to asbestos in talc 18 want, I'll separate them out. 19 19 A I'm just trying to make sure I'm not other than responding to the questions? forgetting something. I don't recall, no. 20 A You can refresh my memory if there's 20 21 any. I -- I can't recall any. 21 Q 2012? 22 Q This is -- you can't recall any. 22 A And again, the question was on 2009, did PCPC have any direct or 23 2.3 asbestos --24 indirect communications with FDA regarding the 24 Q It was on the association between 25 issue of talc and ovarian cancer? 25 ovarian cancer and talc or the asbestos levels or Page 593 Page 595 MR. LOCKE: Other than what we've 1 1 specifications for talc. 2 discussed? 2 A And did you say meetings? 3 MR. TISI: Other than what we -- I'm 3 Q Any communications directly or sorry, I meant to say 2010. I'm sorry. 4 4 indirectly. 5 THE WITNESS: That's what I was confused 5 A I guess --6 on. I was trying to --6 Q I guess what I'm trying to do in kind of 7 7 BY MR. TISI: a summary fashion is to ask you about any Q Yeah, I'm sorry. 8 communications. These are the ones that I've been 8 9 A -- decide if you --9 able to find. I found -- you know, I can go 10 Q Yeah. No, no, it was --10 through your answers --A Okay. Got it. 11 11 A Mm-hmm. 12 Q It was a mistake. 12 Q -- to the FDA questions and do that. 13 A Okay. 13 A Mm-hmm. 14 Q Just to be clear, let me -- I'm going to 14 O Other than that. 15 go through each year --15 A Yeah, and I'm just trying to be careful A Okay. so I'm being -- being accurate. 16 16 Q -- and I want to find out what your 17 17 Q Yeah. communications were in each year. 18 A And I can say I'm not aware of any. I 18 A That's what I thought you were doing. know in 2000 -- when FDA, for example, did their 19 19 20 20 sampling plan, could someone in meeting with the Okay. 21 21 Q So 2010. FDA on something else asked a question, how's it 22 A I want to be careful not to forget 22 going, you know, that's possible. But a meeting 23 something. So the question was anything to do 23 specific to that or something -- some deep 24 24 discussions or work on a specification, not that with --25 Q Let's -- I want to ask you two separate 25 I'm aware of.

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Page 596 Page 598 1 Q Okay. Let me see if I can ask it this 1 discuss with your members whether you had a more 2 way, since we got through 2011. 2 fulsome survey that could be conducted either of 3 3 currently marketed products or of, you know, When is the next time, if ever, PCPC 4 directly or indirectly spoke to the FDA about talc 4 samples that had been stored over time? 5 5 and ovarian cancer? A No, I think our answers -- when we 6 A I'm just trying to think if I'm 6 answered FDA to their questions about testing, et 7 forgetting anything. 7 cetera, I think -- I mean, that addressed it kind 8 8 I'm -- I'm not recalling. Again, there of in an ongoing way. So --9 was the -- FDA did the assessment on the asbestos. 9 Q Okay. You basically said, We tested it 10 There could have been conversations. I --10 as we always did? 11 Q Anything that you -- that you know of as 11 A Yeah. 12 you sit here right now, anything to -- and are 12 Q So, as I understand it, from -- do you 13 prepared to testify to as a -- as a representative 13 know who Susan Nicholson is from J&J? 14 of PCPC? A Nettesheim? 14 15 A Not that I can think of. 15 O No, Nicholson. 16 16 A Oh, no. Q Okay. When is the next time you talked 17 17 about asbestos levels in talcum powder products or Q I understand that J&J had a meeting with 18 asbestos testing in talcum powder products, if 18 FDA in 2018. Do you know anything about that? 19 A That would be this year. 19 ever? 20 MR. LOCKE: With the FDA? 20 Q That would be this year. 21 MR. TISI: With the FDA. 21 A No. 22 22 Q Do you know of any communications that THE WITNESS: Oh, we're aware that FDA the company had with FDA about the lawsuits that 23 did their study, and we're aware, I mean, that our 23 24 members test in a -- on an ongoing basis. 24 have been pending and verdicts that have been 25 BY MR. TISI: 25 obtained against the manufacturers of talc --Page 599 Page 597 1 Q Well, okay, let's -- since you raised 1 A I do not. 2 that issue, FDA did a sampling of -- of certain 2 Q -- and talc products? 3 products bought in the Washington, D.C. area, I 3 MR. LOCKE: Well, just to clarify, when 4 think they said five out of nine, they -- there 4 you say "the company," you're talking about J&J? 5 was -- that wasn't a study, was it? That wasn't a 5 MR. TISI: J&J. 6 study, correct? 6 THE WITNESS: No. 7 A They -- they --7 BY MR. TISI: 8 8 MR. LOCKE: Objection. Q Or -- or Imerys. 9 THE WITNESS: Yeah, that's not exactly 9 Are you aware of any communications 10 what they did. They did -- I think they did from 10 about the lawsuits that have -suppliers, and then they did 30-some products off 11 11 A That those companies have had with FDA? 12 the shelf. 12 Q Yes. 13 BY MR. TISI: 13 A No. 14 Q Right. But they -- the FDA admitted 14 Q Okay. So other -- the last meeting that 15 that that was not a --15 you know of that you had that was formally or 16 A The FDA said it's not exhaustive. 16 informally with the FDA on the issues of talcum 17 Q It's not -- they -- they went further 17 powder products and ovarian cancer was in May of than that. They said it was not -- they could not 18 18 2008? guarantee that this was a true sampling of talcum 19 19 MR. LOCKE: '9. 20 powder products out there, correct? 20 THE WITNESS: '9. 21 MR. LOCKE: Objection. 21 BY MR. TISI: 22 THE WITNESS: They said it was not --22 Q '9. I'm doing what -- what Dr. Bailey 23 not a final answer, yes. 23 did. Sorrv. 24 24 BY MR. TISI: Just to be clear, the last time that 25 Q Right. And in that context, did you 25 you're aware of that PCPC had any direct contact

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Page 600 Page 602 1 with the FDA, either directly or indirectly, was 1 A Correct. 2 the meeting in May of 2009, and any follow-up to 2 Q Now, if go to page 2, there's a section 3 called "Manuscript Reviews." Do you see that? 3 that meeting that was requested by the FDA? 4 A Something specific to that topic. As I 4 A Okay. Yes. 5 5 say, it doesn't mean there weren't -- you know, Q And the second bullet point says: "The б б meta-analysis manuscript -- manuscript prepared by when FDA unveiled their results about talc 7 testing, it doesn't mean somebody didn't ask a 7 Dr. Gross, "and it has a number, "was discussed. 8 8 question or whatever, but --It was agreed on the scientific content of the 9 Q Well, do you know of any questions they 9 manuscript was good, but the format lacked 10 might have asked? 10 clarity," and it goes on and on. Do you see that? 11 A No, I don't. 11 A Yes. 12 Q Okay. Okay. 12 Q Okay. Are you familiar with the study 13 A But, I mean, we have FDA, for example, 13 by Dr. Gross? 14 presents at kind of our meetings sometimes. I 14 A I saw the manuscript in my preparation could see a question being asked. I just --15 15 for this deposition. Q But you don't know of any. 16 Q Now, I'm going to show you there was a 16 17 17 A No, I do not. published article by Gross and Berg. Have you 18 Q All right. So let's go to the second 18 seen that? question, the second area that I said we would 19 19 A I think that sounds familiar. 20 cover, which is studies and consultants. 20 Q May I see --21 A Okay. 21 (Counsel conferring.) 22 Q I'm kind of done with the Citizens 22 BY MR. TISI: 2.3 Petitions --23 Q Okay. I'm going to mark this as Exhibit 24 A Okay. 24 No. 61, and I'm actually going to give you 62, 25 25 which is I think the manuscript that you just may Q -- and contacts with the FDA issue. Page 601 Page 603 1 A Okav. 1 have referred to. 2 Q Let's start in the 1990s. I'm going to 2 (Exhibit Nos. 61 and 62 were 3 go back to Exhibit No. 47, which is the notes from 3 marked for identification.) 4 April 12th, 1994. 4 MR. TISI: Here is your copy. And here 5 A Okay. 5 is 62. 6 Q And that's the task force document. 6 BY MR. TISI: 7 A Yes. 7 Q Now, 61 is the published article, 8 Q And just -- you may have mentioned this 8 correct? A Yes. 9 the last time in your deposition, and I'm sorry, 9 10 I'm trying not to retread old ground, but can you 10 Q And 62 is the internal report, right? 11 tell us what the task force was? 11 A Oh, I'm sorry. I haven't seen 62 yet. 12 A So this is the Talc Interested Party 12 Yes. 13 Task Force, so these are specifically people who 13 Q So one is titled -- the memorandum is 14 have an interest in talc and are willing to pay 14 entitled "Meta-Analysis." Right? 15 for projects as well when required. And these are 15 A Yes. just the member companies, again, with an interest 16 16 Q Okay. And you all paid, at least in part, for this, right? 17 in the topic. 17 Q Okay. And listed on this document are A I believe so, yes. 18 18 19 Johnson & Johnson, Luzenac, American Westminster, Q And if you go to the back, the draft 19 20 paper, the one that was not published, and you go is that --20 21 21 A I don't know. to page 33, it says: "Financial support for this 22 study was provided in part by the Cosmetic Q I don't know that either. 22 23 -- Procter & Gamble Company, Cosmair, 23 Toiletry and Fragrance Association." 24 Colgate Palmolive, Helene Curtis, and then CTFA, A Yes. 24 25 which is PCPC. 25 Q Now --

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Page 604 Page 606 1 MR. GOLOMB: Wait, Chris, the document 1 A As we've discussed, yes. 2 is not up yet. 2 Q And that reflects -- and if you go back 3 3 to my chart here, my -- my timeline, this reflects BY MR. TISI: 4 4 the concerns that talcum powder products may cause Q If you go to page --5 5 MR. GOLOMB: That's the wrong document. ovarian cancer, and there was an active debate 6 6 MR. TISI: 62, yeah. among scientists. That was the concept we talked 7 Yeah, that's right, go to the very end. 7 about earlier. 8 8 It's the Bates 188. A Yes. 9 BY MR. TISI: 9 Q If you go to page --10 Q And the Acknowledgment section 10 MR. TISI: I'm sorry? 11 acknowledges what I think you told us in your 11 (Counsel conferring.) interrogatories: "The financial support for this 12 12 Q Okay. Let's go back to -- if you go to 13 study is provided in part by the Cosmetic, 13 page 192 of the study, the Discussion section. 14 Toiletry and Fragrance Association, correct? A I'm sorry. Which one? 14 15 15 MR. LOCKE: 192. A Yes. 16 Q Okay. Now, the report actually went 16 THE WITNESS: I know. Which document? 17 through peer review, right, and actually was 17 BY MR. TISI: 18 published? 18 Q The actual published study. 19 A Okay. A It looks that way, yes. 19 20 Q Yeah. And when it was published, did 20 Q The authors -- and these are people who 21 you ask -- did PCPC ask that their name be taken 21 were hired by -- paid for by you all, right? 22 off the acknowledgment? Because they're not on 22 A Again, I'm a little confused because it 23 the acknowledgment of the published paper. 23 says J&J. 24 A I see that J&J is. 24 Q Okay. But J&J was actually the -- you 25 I -- I don't know what happened on that 25 know --Page 605 Page 607 1 funding. 1 A Certainly part of, right, industry. 2 Q Well, let's go to the published paper 2 Q Right. So the discussion says: 3 and see what the published paper says. Okay? 3 "Existing evidence linking talc exposure to an A Mm-hmm. 4 4 increased risk of ovarian cancer cannot be viewed 5 Q The one that actually went through peer 5 as scientifically conclusive based upon the available epidemiological studies." Right? 6 review. Right? 6 7 A Yes. 7 A Mm-hmm. Yes. 8 8 Q Okay. First of all, and this -- so that Q Is it your view that the evidence must 9 the jury understands, this is dated 1995. 9 be conclusive before women are told of the 10 10 potential risk in a cosmetic product? 11 MR. LOCKE: Objection. Beyond the scope 11 Q This is some 10 -- 13 years before 12 the -- before the Citizen's Petition. 12 and to form. 13 A Okay. 13 BY MR. TISI: 14 Q Right? 14 Q You may answer the question. Must the 15 A Yes. 15 evidence be conclusive before women are told of 16 Q And so this is -- it says: "The concern 16 the potential risk? that use of talc or talc" -- this is the first 17 17 MR. LOCKE: Same objection. sentence of the abstract -- "the concern that use THE WITNESS: Yeah, I -- I --18 18 BY MR. TISI: 19 of talc or talc-containing substances in the 19 perineal region of women may subject them to an 20 20 Q You know that the standard is that -- we 21 increased risk of ovarian cancer has become an 21 talked about this early on in the deposition -important issue in the study of ovarian cancer." 22 the standard is warnings should be added when 22 23 Is that -- did I read that correct? 23 there may be a risk, correct? 24 24 A That's what it says, yes. MR. LOCKE: Objection. Beyond the scope 25 Q And that's true, right? 25 and form.

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Page 608 Page 610 1 BY MR. TISI: 1 says: "However, all the meta-analysis arrive at a 2 Q You're told -- you know that, right? 2 relative risk rate of 1 with a 95 percent 3 MR. LOCKE: Same objection. 3 confidence interval excluding the null." 4 4 That's basically saying that all the BY MR. TISI: 5 Q You actually publish -- PCPC publishes a 5 meta-analysis done as of that time showed an 6 labeling book for its members, correct? 6 increased risk, correct? 7 MR. LOCKE: Objection. 7 MR. LOCKE: Objection. 8 THE WITNESS: The labeling book deals THE WITNESS: Well, that's the 8 meta-analysis. That's not the individual studies. with current labeling requirements. 9 9 10 10 BY MR. TISI: BY MR. TISI: 11 Q Right. And you know that warnings 11 Q The purpose of a meta-analysis is to should be added when there may be a risk, correct? combine studies to increase the power of a study 12 12 MR. LOCKE: Objection. Beyond the scope 13 13 to determine a risk, right? 14 14 MR. LOCKE: Objection. and to form. THE WITNESS: Yeah, that seems like a 15 THE WITNESS: I mean I'm not an 15 16 legal labeling issue that's not anything --16 epidemiologist, but I would say, yes, that's their 17 BY MR. TISI: 17 basic purpose. 18 Q But you were responding to a Citizen's 18 BY MR. TISI: Petition regarding labeling, right? You were 19 19 Q And the last page on page 193, and this is of a 1995 article funded by you all. 20 responding to that? 20 21 A We were responding to the science piece 21 MR. LOCKE: Objection. 22 22 THE WITNESS: Oh, yeah, it's -- I'm not of --Q Right. And I asked you what the sure what happened here. The authors changed, the 23 23 24 standard was because doctor -- Dr. Epstein was 24 things changed, and the -- the acknowledgments 25 asking for a label change. Right? 25 changed. So I -- I don't want to say this was Page 609 Page 611 1 MR. LOCKE: You're asking her what you 1 funded by PCPC. That's not what it says. And 2 asked her? 2 there's definitely a change in authorship here, so 3 BY MR. TISI: 3 things changed. 4 BY MR. TISI: 4 Q No, I -- you know that Dr. Epstein was 5 asking for a label change to add a warning about a 5 Q The last sentence says: "The -- thus, 6 potential risk, right? б the body of knowledge found in the medical 7 A I know that that's what he was asking 7 literature does not unequivocally support the 8 8 hypothesis that talc use puts women at an for, correct. increased risk of ovarian cancer. However, the 9 Q And you responded and opposed that, 9 10 10 results of this meta-analysis do suggest the correct? 11 possibility of an increased ovarian cancer due to MR. LOCKE: Objection. 11 12 THE WITNESS: Based on the science. 12 peritoneal -- perineal talc use." 13 BY MR. TISI: 13 Do you see that? 14 Q Right. And I asked you before, did you 14 A Yes. 15 know the standard, correct? 15 Q And these were the same authors at least that were the people that you all hired to do a 16 A And I think I said I didn't, that that 16 meta-analysis, correct? 17 was a legal --17 Q Okay. And so you responded to the A Well, I think we hired Dr. Gross, but I 18 18 19 petition not knowing what the standard was. don't think we hired Dr. Berg, so that's why I'm 19 20 MR. LOCKE: Objection. 20 saying I'm not sure. THE WITNESS: We responded by offering 21 21 Q And Dr. Berg -- Dr. Berg, I will 22 scientific -- expert epidemiologists' opinion on 22 represent to you, was -- was a doctoral student of 23 what the epidemiology shows. 23 Dr. Gross. And that's made clear in other 24 24 BY MR. TISI: documents. 25 Q Now, at the last sentence here, Dr. Berg 25 A Okay.

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Page 612 Page 614 Q He was basically given coauthorship, but 1 1 that? 2 it was really Dr. Gross. 2 A Yes. 3 So can you say -- these appear to be the 3 Q And at this time frame, as in others, 4 same. This one is March 17, 1994. This 4 this was an important issue, right? That's why 5 meta-analysis -- published meta-analysis is 1995. 5 you guys were meeting. б One says it's sponsored by J&J, the other one says 6 A That's what we were talking about, yes. 7 7 Q And other than the Berg article which we 8 8 just discussed, are you aware of any industry-Do you agree that this is likely the same study? 9 sponsored epidemiological study or meta-analysis 9 10 that actually looked at the question specifically 10 A I think it looks like it's related, yes. Q Okay. So this is one study that you 11 11 of whether ovarian cancer and talc were related? authored -- that you were involved with. 12 12 A Industry study, no. 13 Let's go through another one. 13 Q Given the importance of the issue, don't MR. LOCKE: Objection. 14 you find that a little odd? 14 15 BY MR. TISI: 15 MR. LOCKE: Objection. 16 Q Let's go back to the task force 16 BY MR. TISI: 17 document. 1994. 17 Q It was discussed, right, should we do a 18 The last page, number 4 under the --18 study? 19 this is under a heading entitled "Future Research 19 A Right. I don't know what the follow-up Needs." Do you see that? was, but, I mean, I guess the question is, is it 20 20 21 A The last page? 21 going to make a difference and is it going to be 22 22 Q If you go to page -criticized for being an industry study? A I see "Future Research Needs." Q Well, if the industry study found what 2.3 23 24 Q Right. And if you go to the last page, 24 everyone else said, then everyone would be on the 25 25 same table, right? They would all -- everyone number 4. Page 613 Page 615 1 1 would all agree. A Okay. 2 Q Okay. Do you see that? 2 MR. LOCKE: Objection. 3 3 BY MR. TISI: Q Well, let me ask you this: Are you 4 Q It says -- I don't know who MNordhauser 4 5 aware that Dr. Wynder did in fact propose a study? is, but that seems to be a person, right? 5 6 A I think it's Mary Ann Nordhauser. 6 A I'm not aware. 7 Q Okay. She pointed out: "The importance 7 Q Do you know at the time you mentioned --8 of considering other research directions in which 8 now doctor -- who is Dr. Wynder? 9 the task force should be involved. Ms. Nordhauser 9 A I don't know. 10 suggested the task force consider sponsoring 10 Q Do you know Dr. Wynder was with the 11 further epidemiological studies. It was noted 11 American Health Foundation? 12 that Dr. Ernst Wynder discussed an outline of such 12 A I guess I do now. 13 a research proposal at the ISRTP symposium. Mike Q You know the American Health Foundation 13 14 Chudkowski agreed to discuss the developments of 14 was the same foundation where Dr. Muscat worked? 15 such a proposal with Dr. Wynder." 15 16 Do you see that? 16 Q Do you know that Dr. Muscat proposed an epidemiology study to J&J to follow up exactly on 17 Yes. 17 Q Okay. And was it important during the 18 this issue in 1994, 1995? 18 1990s for the CTFA and the members of the talc 19 19 A No, I don't know that. I mean, I 20 task force to do research into the area that we've 20 believe that. I just don't know that. 21 21 been discussing, ovarian cancer and talc? (Exhibit No. 63 was marked for 22 A I guess I think it was discussed to see 22 identification.) 23 if -- you know --23 BY MR. TISI: 24 Q Well, she says: "The importance of 24 Q I'm going to show you Exhibit No. 63. 25 considering research directions." Do you see 25 Now, I'll represent to you, because I

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Page 616
                                                                                                         Page 618
                                                              1
 1
       don't like to misrepresent things, that the --
                                                                         MR. TISI: Okay. I thought it was -- I
 2
       that this is a composite exhibit. Okay. If you
                                                              2
                                                                   thought it was December 1994, but okay.
 3
                                                              3
                                                                         So -- and there's a -- there's actually
       notice the top is a grant application, but if you
 4
       notice the Bates numbers are -- don't coincide
                                                              4
                                                                   a letter sent to J&J listing this out, and I won't
 5
       directly with the attachment.
                                                              5
                                                                   go into detail about it.
 6
              We discussed it with Dr. Muscat the
                                                              6
                                                                   BY MR. TISI:
 7
       other day, so there is -- this was a -- he used a
                                                              7
                                                                      Q But my question is this appears to be a
 8
                                                              8
       grant application to Johnson & Johnson, but the
                                                                   follow-up --
                                                              9
 9
       actual proposal is attached.
                                                                         MR. TISI: Do you have a copy of that
10
           A Okay.
                                                            10
                                                                   letter?
11
           Q Okay?
                                                            11
                                                                         Okay. Could we take a break for one
                                                            12
                                                                   minute while we get a copy of the letter?
12
           A Yes.
13
           Q
              And you see that this is a proposal from
                                                            13
                                                                         THE VIDEOGRAPHER: The time is 2:06 p.m.
14
       1994?
                                                            14
                                                                   We're going off the record.
                                                            15
                                                                         (Recess.)
15
           A Yes.
                                                                         THE VIDEOGRAPHER: The time is 2:16 p.m.
16
           Q This would have been within six months
                                                            16
17
       of the CTFA Talc Interested Party Task Force --
                                                            17
                                                                   We're back on the record.
18
              MR. DUFFY: Counsel, can you confirm
                                                            18
                                                                   BY MR. TISI:
19
                                                            19
       that what's in these exhibits is a composite
                                                                      Q Doctor, I don't want to belabor the
                                                                   point because I know we've been going a little
20
       exhibit --
                                                            20
21
              MR. TISI: Absolutely. Absolutely. It
                                                            21
                                                                   while, and I've got to turn my time over to other
22
       is two documents. The one is the actual
                                                            22
                                                                   people.
                                                            23
                                                                         But do you know whether or not J&J --
23
       application itself.
                                                            24
24
              MS. FRAZIER: Are there any other copies
                                                                   first of all, the study that you have in front of
25
                                                            25
                                                                   you is a case controlled study.
       of that since --
                                             Page 617
                                                                                                         Page 619
 1
                                                              1
              MR. TISI: Yeah. Yeah.
                                                                       A Okay.
 2
              MR. DUFFY: This one kind of came apart.
                                                              2
                                                                       Q Do you -- well, do you see it? It's
 3
              MR. TISI: Okay. It was testified to by
                                                              3
                                                                    entitled "Proposal for a Case Controlled Study of
                                                                    Talcum Powder Use in Ovarian Cancer."
 4
       Dr. Muscat the other day, so they refer to the
                                                              4
 5
                                                              5
                                                                          MR. LOCKE: If you go back to page 78 at
       same thing.
 6
              The first -- and just to be clear for
                                                              6
                                                                   the bottom there.
 7
       the record, the top exhibit is a grant application
                                                              7
                                                                          THE WITNESS: This one? Yep. Okay. I
 8
       entitled "Talcum Powder Use in Ovarian Cancer,
                                                              8
                                                                    see it, yes.
 9
       Joshua Muscat, Research Scientist," on behalf of
                                                              9
                                                                    BY MR. TISI:
10
                                                            10
                                                                       Q So there's a study -- this is actually a
       the American Health Foundation.
11
                                                            11
                                                                    study proposal, okay?
              There is actually a letter that goes
12
       along with it as well, and attached is that actual
                                                            12
                                                                       A Yes.
13
       proposal for case controlled study of talcum
                                                            13
                                                                       Q So just so we have the time frame down,
14
       powder use and ovarian cancer.
                                                            14
                                                                    the -- in 1994, you all had a meeting. There was
15
              MR. DUFFY: Thank you.
                                                            15
                                                                    a suggestion that J&J follow up and see whether or
16
              MR. TISI: You're welcome.
                                                            16
                                                                    not an additional study could be done by
17
       BY MR. TISI:
                                                            17
                                                                    Dr. Wynder's group. This is Dr. Wynder's group,
                                                            18
                                                                    the American Health Foundation. They proposed a
18
           Q And I'll represent to you that both of
       these documents are dated 2000 and -- actually,
19
                                                            19
                                                                    study, and the study was a case controlled study.
20
                                                            20
       1994.
                                                                          Does that appear to be true?
21
           A Okay.
                                                            21
                                                                          MR. LOCKE: Objection.
22
              MR. LOCKE: Well, one says, not the --
                                                            22
                                                                          THE WITNESS: That appears to be true.
       January 31st, 1995.
23
                                                            23
                                                                    BY MR. TISI:
24
              MR. TISI: Okay. The second one?
                                                            24
                                                                       Q Did -- now, the study, if you go back
25
              MR. LOCKE: Yes.
                                                            25
                                                                   one page, is about a $400,000 study.
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61 (Pages 616 to 619)

Page 620 Page 622 1 A That's what it says, yes. 1 many possible confounders which had previously 2 O All right. Now, I have a document 2 been ignored. The study will take two and a half 3 here -- first of all, had you ever -- before 3 years to complete and cost nearly \$400,000." 4 coming here today, had you heard about this study 4 Did I read that so far? 5 5 or know anything about it? A Yes. 6 A I don't believe so, no. 6 Q "We at J&J have reviewed the proposal 7 Q Okay. I'm going to provide you with a 7 and believe the study could help clarify the many 8 document, page -- it's Exhibit No. 15, and it says 8 obvious shortcomings in the previously reported "Draft Never Sent," but I'm curious as to whether 9 9 studies. For as long as I've been on the Talc 10 10 or not there was any other documents related to Interested Party Task Force, we have discussed 11 11 ways to improve our understanding of cosmetic talc that. use. I think the task force should sponsor the 12 (Exhibit No. 64 was marked for 12 13 identification.) 13 study as an industry initiative. Would you please 14 MR. LOCKE: This is also marked 63. 14 poll the members about the idea and put this 15 MR. TISI: Right -- oh, I'm sorry. Let subject on our upcoming task force meeting and 15 16 me -- what number are we at now? 16 agenda?" 17 MR. LOCKE: 64. 17 Do you see that? 18 MR. TISI: See without my -- so what's 18 A Yes. 19 19 Q And I read that correctly? the next one we're at? 20 MR. LOCKE: 64 is the one we're -- that 20 A Yes. 21 21 Q Okay. Do you know whether or not J&J one should -- would be. 22 MR. TISI: Thank you, Tom. 22 ever brought to the attention of the -- the CTFA the \$400,000 well-designed, carefully designed 23 BY MR. TISI: 23 study that Dr. Muscat drafted when he was with the 24 O Let me see if this somehow raises a --24 25 the specter to you that perhaps maybe this was 25 American Health Foundation? Page 621 Page 623 1 discussed with Dr. Gettings. First of all, this 1 MS. FRAZIER: Object to form. 2 is --2 THE WITNESS: I'm not aware. I don't 3 MR. GOLOMB: Could we just get that 3 believe I've seen this or seen discussion of it. 4 document up on the screen? 4 BY MR. TISI: MR. TISI: Yeah, May 5th -- it's 139. 5 5 Q Is this the kind of study that the -- I 6 BY MR. TISI: 6 mean, we talked about the fact that the CTFA and 7 7 Q And it says -- it's a -- it's a letter, PCPC was very interested in the science 8 and it says "Draft Never Sent" on top. So I don't 8 surrounding talc. Right? 9 want to -- I don't know whether you got it or you 9 A Yes. 10 didn't get it or you got another version of it or 10 0 And have been interested for decades, 11 whatever. I haven't seen anything in the records 11 right? 12 relating to this, but --12 A Yes. 13 A I haven't --13 Q Do you have any reason to believe that 14 Q -- I don't know whether or not anything 14 such a study had been brought to the attention of in your -- in your travels you may have found 15 15 the CFTA that such a study would not have been 16 something. 16 funded and done? It says, Dr. Gettings: "Dear Steve: 17 17 A I really don't know. I mean, I think This provides you with a copy of a talc proposal 18 you really would have to -- yeah, I can't say 18 19 prepared by Dr. Joshua Muscat and Dr. Ernst Wynder 19 without having had that experience of bringing it 20 of the American Health Foundation. They are 20 and asking who was willing to do the funding. 21 21 proposing a new more definitive epidemiology study Q Has anybody -- has J&J ever proposed a 22 examining the hypothesized link between hygenic 22 study, in all of your experience with them, or 23 use of cosmetic talcum powder and the incidence of 23 proposed an action that CTFA decided it was not 24 ovarian cancer. It is a very carefully designed 24 going to do, that you can think of? 25 study with special attention paid to -- paid to 25 A We -- we -- I mean just overall, not

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	Page 624		Page 626
1	outside of the area of talc, I mean sometimes we	1	identification.)
2	talk about studies and people either decide to do	2	BY MR. TISI:
3	them or not.	3	Q This is a 2003 study. And I only have
4	Q Okay. So but this study that was	4	one copy, but since I know it by heart, I'm not
5	proposed by Dr. Muscat to help understand the	5	going to need it.
6	issue was never sent to the members of the task	6	Do you know whether or not this is a
7	force to the best of your knowledge?	7	study I assume you saw it. You're familiar
8	A I'm I'm not aware of it. I don't	8	with that study, it's a 2003 study by
9	believe I've seen this before.	9	Dr. Huncharek?
10	Q Do you know why I mean in all this	10	A I yes.
11	time, decades have gone by, and the the	11	Q Is that a study that were you aware
12	company the companies involved in the task	12	of that study before it was published?
13	force have never done an epidemiology study to	13	A No.
14	study perineal talc and ovarian cancer?	14	Q Okay. Was was PCPC in any way made
15	A I guess I can't answer that. I mean, I	15	aware of the study before it was published?
16	guess the question could be, you know, would it	16	A No.
17	make a difference and would an industry study be	17	Q Okay. Did PCPC we discussed the two
18	taken without it being assumed that it wasn't as	18	papers from Dr. Huncharek and Muscat that was in
19	good as another study? I don't know. But I don't	19	the letter from the e-mail from Mr. Glenn.
20	know.	20	A Yes.
21	Q Okay. Well, that doesn't stop you all	21	Q I can attach those two studies here.
22	from doing studies, does it?	22	MR. TISI: Do you have those two
23	A Well, it doesn't, except that it I	23	studies?
24	mean it it becomes an issue.	24	(Counsel conferring.)
25	Q So you could always hire an outside	25	MR. TISI: 51 or 52, if you can get
23	· · · · · · · · · · · · · · · · · · ·	23	1VIX. 1131. 31 of 32, 11 you can get
	Dama COF	1	Daga (27
	Page 625		Page 627
1	group to do it, right, and not have any role in	1	those.
2	group to do it, right, and not have any role in the in the design of the study, no role in the	2	those. BY MR. TISI:
2	group to do it, right, and not have any role in the in the design of the study, no role in the editing of the study, no role no approve	2 3	those. BY MR. TISI: Q Now, other than being aware of them
2 3 4	group to do it, right, and not have any role in the in the design of the study, no role in the editing of the study, no role no approve approval or non-approval of the text, right? I	2 3 4	those. BY MR. TISI: Q Now, other than being aware of them before they were published, was PCPC involved in
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63 (Pages 624 to 627)

	Page 628		Page 630
1	A He may have been asked about it. I'm	1	(Exhibit No. 66 was marked for
2	not sure, but we did not fund any.	2	identification.)
3	Q There was a study that Dr. Mossman	3	BY MR. TISI:
4	proposed. Are you familiar with the Shukla paper?	4	Q First of all, if you go to page 10, it
5	A Not by that name.	5	says actually, hold on a second.
6	Q It's a Mossman it's a published	6	Okay. On page 12, it says: "Around
7	Mossman study.	7	April 1997, CTFA sought the assistance of
8	A Okay.	8	consultant epidemiologists to evaluate a study on
9	Q Are you aware that Dr. Mossman had	9	powder exposure and perineal cancer."
10	proposed a follow-up study that industry declined	10	A I'm sorry, page 12?
11	to fund?	11	·
12			Q Page 12.
		12	A Oh, second paragraph. Okay.
13	Q Have you ever understood why a	13	Q Do you see that?
14	company or what do you understand about that	14	A Yes.
15	study?	15	Q Do you know what study that refers to?
16	A I I am hard-pressed to remember what	16	A April '97. I should know.
17	it was about.	17	Q The only study I found is the Cooke
18	Q Do you understand that she wanted to	18	study. Does that sound familiar?
19	look at different kinds of talc and how it reacted	19	A Oh, yeah. I think so.
20	to ovarian cancer cells?	20	Q Would that have been the Cooke study?
21	A I I just don't remember.	21	A I couldn't tell you off the top what
22	Q Do you know whether or not why PCPC	22	year the Cooke study was, but it would be
23	decided not to fund that study?	23	because I'm not thinking of any other event, I
24	A If that's as I remember, because that's	24	think it would be a single study that
25	how I remembered, is there was one study, and we	25	Q I'm going to show you the Cooke study,
	Page 629		Page 631
1	Page 629 ask our people and if they want to fund, and	1	Page 631 and it's Exhibit No. 67.
1 2		1 2	
	ask our people and if they want to fund, and		and it's Exhibit No. 67.
2	ask our people and if they want to fund, and basically it's you know, either they do or they	2	and it's Exhibit No. 67. (Exhibit No. 67 was marked for
2	ask our people and if they want to fund, and basically it's you know, either they do or they don't, and we would not necessarily know, and nor	2 3	and it's Exhibit No. 67.  (Exhibit No. 67 was marked for identification.)  BY MR. TISI:
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Page 632 Page 634 1 wasn't helpful, candidly, but I can go back and 1 MR. LOCKE: We will see. Okay. 2 figure it out. 2 BY MR. TISI: 3 3 BY MR. TISI: Q Okay. One last couple of questions, and 4 Q It sought the assistance of consulting 4 then I'm going to kind of be done with it. 5 5 epidemiologists to evaluate the article. Do you I asked you whether or not the industry б know which epidemiologists they were? 6 or CTFA or individually the industry members had 7 7 A I don't. done an epidemiology study studying ovarian cancer 8 8 and talc, and you had indicated that you were Q Do you know whether it was Dr. Muscat? 9 9 A I don't think so. unaware of any, correct? Q Do you know that Dr. Muscat wrote a 10 10 A That's correct. 11 letter to the editor regarding the Cooke paper? 11 Q Are you aware of any study in which the A No, I don't -- I don't think I knew company did any toxicology studies on animals and 12 12 13 that. I -- I wasn't aware -- again, I wasn't 13 ovarian cancer? 14 14 here, so --A The -- through CTFA, the -- it was the 15 Q I understand. I'm asking you with your monkey study was -- I guess two monkey studies or 15 16 hat on as PCPC. 16 one -- one pre-study, one study on translocation. 17 17 A No, totally agree. I just -- I'm just Q Okay. But none looking at cellular --18 saying I wasn't aware that we used Dr. Muscat 18 whether or not talc or any talc constituent causes 19 before 2000. cellular changes in ovarian cancer cells in 19 20 Q Okay. I'm going to show you -- I'm 20 animals? 21 going to put this -- and we will get an exhibit. 21 A I can't think of anything. 22 22 But here is a letter to the editor on Q Okay. And that would be something that 23 2.3 certainly could be done, right? the --24 MR. TISI: Can you put it up? 24 A I mean something --25 (Counsel conferring.) 25 MR. LOCKE: Objection. Page 635 Page 633 1 BY MR. TISI: 1 THE WITNESS: Yeah, something could be 2 Q I'm going to put it up on the screen and 2 done, but you'd have to -- I mean, one would need 3 we'll just have to substitute it. 3 to think about that further as to what could be 4 And this will be Exhibit No. 68. 4 done, if it would make sense. If it would, you 5 (Exhibit No. 68 was marked for 5 know, really shed any light on --6 identification.) 6 BY MR. TISI: 7 BY MR. TISI: 7 Q Well, I mean, without being facetious, 8 Q And here is a letter to the editor in 8 you all had about 40 years to think about it. 9 1997 from Dr. Muscat and Dr. Wynder from the 9 The question is, did you ever talk with 10 American Health Foundation. 10 amongst the members and say, Maybe we ought to do 11 Do you see that on the screen? 11 an animal study seeing whether or not talcum 12 A Sort of, yes. 12 powder products or any constituent of those products cause cellular changes in ovaries of any 13 Q I'm not going to ask you to comment on 13 14 14 particular animal? it. 15 A Right. 15 MR. LOCKE: Objection. 16 Q I'm asking you do you believe that --16 THE WITNESS: I -- I'm not sure there that -- I'm trying to understand. 17 wasn't something done. Not by us, but -- no, we 17 Would Dr. Muscat and the American Health 18 didn't -- we didn't do anything. 18 19 Foundation have been the epidemiologists with whom 19 BY MR. TISI: 20 you likely consulted to critique the Cooke paper? 20 Q Okay. Any -- there was a discussion in 21 21 A I guess I just would have to say that's one of the -- in the e-mail that Mr. Glenn sent 22 possible. 22 you in 2005 asking whether or not CTFA would do a 23 MR. TISI: Okay. Counsel, I'm going to 23 dose-response study, because that was one of the 24 ask you, on behalf of PCPC, if you could clarify 24 Bradford Hill criteria that you all thought didn't 25 that for us, if you don't mind. 25 -- didn't support causation, and asked whether you

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Page 636 Page 638 1 would fund a study by Rothman or something that 1 Q That -- that report that was done by 2 could be published on dose-response. 2 Dr. Rothman and Pastides and Samet was never 3 Did you all discuss that? 3 submitted to a journal for peer review, was it? 4 MR. LOCKE: Objection. 4 MR. LOCKE: Just to clarify, you're THE WITNESS: We had Dr. Rothman's and 5 5 talking about the 2000 NTP? б Dr. Samet's and Dr. Pastides' paper. 6 MR. TISI: Correct. 7 BY MR. TISI: 7 THE WITNESS: Correct. It was submitted 8 8 to NTP. Q From 2000? 9 A His assessment. And we -- right, he --9 BY MR. TISI: 10 he did not propose reasonable terms that -- for us 10 Q But it was never submitted for 11 to take that forward. 11 publication in any peer-reviewed journal. Q Okay. Could you explain that a little 12 12 A That's correct. 13 more, because I'm not really sure --13 Q Okay. And you declined to support 14 A He wanted to charge such an incredible that -- that submission for cost reasons, correct? 14 amount, it was far out of the ballpark of being A Only because it was very unreasonable. 15 15 16 reasonable. 16 Q Okay. Did you ever propose to 17 Q Okay. Well, I -- I'm still not 17 anybody -- did anyone ever propose to PCPC or 18 understanding. Did he propose to do a follow-up 18 anybody else that a dose-response study actually study to look at dose-response? 19 be undertaken? 19 20 A No. No, it wasn't -- it wasn't that. 20 A I think that was talked about, and I 21 He was proposing to turn his -- the submission 21 think there was concern that it was something that 22 that he was -- coauthored into a publication. 22 had been done by somebody else, and should we be Q Okay. And how much did he charge -- did doing that. And again, when I say the cost was 23 23 24 he want to charge? 24 high, it was just well out of the bounds of what 25 A \$100,000. 25 you would expect. I mean it wasn't even close. Page 637 Page 639 1 Q And you all decided thanks but no 1 Q Well, let me ask you this, and I will 2 thanks? 2 represent to you -- and I don't have a copy of it 3 A That's not a reasonable number. 3 right here. Maybe I do. This is Exhibit No. 69. 4 Q Okay. And then in 2005, Luzenac came 4 5 5 back to you and said, you know, We really think (Exhibit No. 69 was marked for 6 it's important to publish a study on dose-6 identification.) 7 response. Would you consider it? 7 BY MR. TISI: 8 And that was -- we could pull it out, 8 Q I will represent to you in 2009, 9 but that was the e-mail we talked about Huncharek 9 Drs. Huncharek and Muscat proposed all kinds of 10 and Muscat. Do you remember that? 10 studies that could be done to further eluciate --11 A Yes. elucidate the issue. Smoking and ovarian risks, 11 12 Q Did you go back to the well and say, you 12 hysterectomy and tubal ligation, completion and 13 know, Maybe you ought to publish it and do a publication of Rothman's dose-response analysis, 13 14 published study on dose-response? 14 et cetera, and then they subsequently propose their own dose-response study. 15 MR. LOCKE: Objection. 15 THE WITNESS: No. Again, we had the 16 16 Do you know whether any of those were assessment done, but we -- no, we did not go brought -- any of these proposals were brought to 17 17 18 forward to have that made into a publication. the PCPC? 18 19 BY MR. TISI: 19 A I'm not aware that they were. Q That publication was never subject to 20 Q Okay. Do you currently have any studies 20 21 that you are -- have either considered -- well, peer review, was it? 21 22 A No. I mean it was -- it was a --22 let me ask you this: Other than the ones we've discussed, can you think of any study that was 23 Q I'm sorry. Let me rephrase the 23 proposed to the PCPC or by the PCPC relating to 24 24 question. 25 A Yeah. 25 the -- any issue relating to ovarian cancer and

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	Page 640		Page 642
1	talc?	1	A We didn't do we didn't do one. I
2	A I'm sorry, what was the first part of	2	mean, there wasn't I guess it wasn't thought it
3	your question?	3	would help or would be seen favorably coming from
4	Q Do you know of any study that was either	4	the industry or
5	proposed to the PCPC or by the PCPC relating to	5	Q Okay. Any studies relating to the
6	any issue regarding talcum powder products and	6	purity of talc from potential carcinogens,
7	ovarian cancer?	7	including asbestos, did you ever sponsor
8	A I mean, I guess the monkey study, and	8	discuss any studies about that?
9	then	9	A I mean, I think that goes back to when
10	Q No, that wasn't done. That was	10	the specification was being put in place and all
11	proposed.	11	the testing was done, and then from then on, it
12	A Oh, that wasn't done.	12	was an ongoing work that was done by the industry,
13	Q Yeah.	13	by the individual companies to
14	A I think not a maybe not a hard core	14	Q No, I you're thinking of something
15	well, the ones you've talked about, I mean the	15	I'm not talking about testing. I'm talking about
16	Mossman. But again, I'm not sure there's any that	16	any publications done to validate and study
17	came to proposal. I mean, I guess it's the things	17	whether or not to test it was effective in
18	we're talking about now, right?	18	removing potential carcinogens, including
19	Q Well, I'm asking if there's anything	19	asbestos?
20	else.	20	A Any publication?
21	A Right.	21	Q Yeah.
22	Q I mean, I'm trying to understand what	22	A I'm not
23	you know. Right?	23	Q Or studies.
24	·	24	A sure what you mean by publication.
25	So so are there I've tried to pull out some things that	25	Q Or studies. Surveys, studies, anything
23		23	
	Page 641		Page 643
1	A Right.	1	like that.
2	Q I could see from the records.	2	A I think that we relied on
2	<ul><li>Q I could see from the records.</li><li>A Right.</li></ul>	2	A I think that we relied on Q The tests themselves.
2 3 4	<ul><li>Q I could see from the records.</li><li>A Right.</li><li>Q But I didn't live your life</li></ul>	2 3 4	<ul><li>A I think that we relied on</li><li>Q The tests themselves.</li><li>A Right, that the companies were carrying</li></ul>
2 3 4 5	<ul> <li>Q I could see from the records.</li> <li>A Right.</li> <li>Q But I didn't live your life</li> <li>A Right.</li> </ul>	2 3 4 5	<ul> <li>A I think that we relied on</li> <li>Q The tests themselves.</li> <li>A Right, that the companies were carrying out ongoing.</li> </ul>
2 3 4 5 6	<ul> <li>Q I could see from the records.</li> <li>A Right.</li> <li>Q But I didn't live your life</li> <li>A Right.</li> <li>Q so I don't know what what you</li> </ul>	2 3 4 5 6	A I think that we relied on Q The tests themselves. A Right, that the companies were carrying out ongoing. MR. TISI: All right. If you want to
2 3 4 5 6 7	<ul> <li>Q I could see from the records.</li> <li>A Right.</li> <li>Q But I didn't live your life</li> <li>A Right.</li> <li>Q so I don't know what what you know.</li> </ul>	2 3 4 5 6 7	A I think that we relied on Q The tests themselves. A Right, that the companies were carrying out ongoing. MR. TISI: All right. If you want to take a break, I think I'm done.
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	Page 644		Page 646
1	I think we had gone to them, and they just made it	1	learn why it was that one or more of your members
2	clear that it was going to be very, very expensive	2	rejected the Wynder/Muscat study?
3	if we wanted so we didn't carry it as far as to	3	A No.
4	a proposal.	4	Q All right. Now, in in addition to
5	Q Okay. You said in response to	5	Rothman and in addition to Wynder and in addition
6	Mr. Tisi's question that it was approximately	6	to Muscat, there's a Dr. Wehner, correct, or
7	\$100,000. Where did you get that number if not	7	Wehner?
8	from a proposal?	8	A Wehner, yes.
9	A I I just just kind of a verbal.	9	Q And that's spelled W-E-H-N-E-R?
10	Q From who?	10	A Correct.
11	A I think J&J actually went back and asked	11	Q All right. And the Wynder/Muscat
12	him and and got a verbal on it.	12	proposal was sometime in the early to mid-'90s, is
13	Q When and when was that?	13	that your understanding?
14	A It was after the NTP meeting.	14	A Whatever it was that I just saw. As I
15	Q Okay. And were you with with PCPC at	15	say, we never we PCPC didn't see it, so I
16	that time?	16	would rather look at what it was than try to go by
17	A Yes.	17	memory.
18	Q All right. So that was shortly after	18	Q Okay. Well, let me ask you this: You
19	you went onboard with PCPC?	19	have and I've asked you before about
20	A No, I started no, that was in 2000	20	Dr. Wehner, and you've reviewed some of the
21	or probably 2000 I'm sure it was 2001.	21	documents from him as well, correct?
22	Q Okay.	22	A Yes.
23	A I started PCPC in 1997.	23	Q And those documents begin in the early
24	Q All right. And the Wynder/Muscat	24	to mid-1990s, correct?
25	proposal, why was that rejected?	25	A Dr. Wehner did the study at Battelle, so
	Page 645		D (40
	1490 013		Page 647
1	A I I don't believe we ever saw that	1	
1 2		1 2	that was in the early '80s.  Q Okay. Well
	A I I don't believe we ever saw that		that was in the early '80s.
2	A I I don't believe we ever saw that PCPC ever saw that.	2	that was in the early '80s.  Q Okay. Well
2 3	A I I don't believe we ever saw that PCPC ever saw that.  Q But at least one or more of your members	2	that was in the early '80s.  Q Okay. Well A Or mid-'80s.
2 3 4	A I I don't believe we ever saw that PCPC ever saw that. Q But at least one or more of your members did?	2 3 4	that was in the early '80s.  Q Okay. Well A Or mid-'80s. Q he was
2 3 4 5	A I I don't believe we ever saw that PCPC ever saw that. Q But at least one or more of your members did? A That's what it it looked like that	2 3 4 5	that was in the early '80s.  Q Okay. Well A Or mid-'80s. Q he was A Mid-'80s.
2 3 4 5 6	A I I don't believe we ever saw that PCPC ever saw that. Q But at least one or more of your members did? A That's what it it looked like that J&J saw it, yes.	2 3 4 5 6	that was in the early '80s.  Q Okay. Well A Or mid-'80s. Q he was A Mid-'80s. Q he was retained by the CFTA in the
2 3 4 5 6 7	A I I don't believe we ever saw that PCPC ever saw that. Q But at least one or more of your members did? A That's what it it looked like that J&J saw it, yes. Q And do you know why from your review	2 3 4 5 6 7	that was in the early '80s.  Q Okay. Well A Or mid-'80s. Q he was A Mid-'80s. Q he was retained by the CFTA in the early '90s, correct?
2 3 4 5 6 7 8	A I I don't believe we ever saw that PCPC ever saw that. Q But at least one or more of your members did? A That's what it it looked like that J&J saw it, yes. Q And do you know why from your review of the records, why that proposal was rejected? A No. Again, I don't think we ever saw it.	2 3 4 5 6 7 8	that was in the early '80s.  Q Okay. Well A Or mid-'80s. Q he was A Mid-'80s. Q he was retained by the CFTA in the early '90s, correct? A In addition to doing that study, he was retained in 2000, and he was retained at he I know we paid for his travel to the ISRTP
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Page 648 Page 650 1 A I mean, we hired him, so we had 1 case controlled study? 2 proposals, I guess. So, yes, documents. 2 A Maybe vaguely. 3 Q Did -- it's really -- it's not a trick 3 Q Okay. And do you recall -- does it help 4 question. I'm just trying to understand that 4 refresh your recollection that in that letter 5 you -- you in fact saw letters from Dr. Wehner to 5 dated in 1994, that in addition to recommending 6 the CFTA outlining what it is that he was 6 the study, Dr. Wehner put some parameters on it 7 proposing that be done, correct? 7 and said it would be easy to do and that you could 8 A I can think of at least one, yes. 8 get the results back within six months? 9 9 Q Okay. And included in those letters A I think that sounds vaguely familiar, were also comments from Dr. Wehner about comments 10 10 but I don't remember the details of what -- what 11 that the CFTA -- that Luzenac at that time, the 11 he was proposing. 12 12 predecessor of Imerys, some of the things that Q And that study was never done, correct? 13 they were going to say publicly about the defense 13 A Again, I would really feel better seeing 14 of talc and ovarian cancer, correct? Do you what it is, so that -- but a study by doctor -- a 14 15 recall those? 15 case controlled study by Dr. Wehner was never 16 A I'm not sure what you mean. I'm --16 17 Q Okay. Do you recall in one of those 17 Q Right. And so -- and a case controlled 18 letters that Dr. Wehner, in addition to 18 study by Dr. Wynder or Dr. Muscat was never done, 19 Dr. Rothman, in addition to Dr. Wynder, in 19 20 addition to Dr. Muscat, that Dr. Wehner also 20 A Again, PCPC was not even aware of that 21 recommended that the CFTA and J&J and other 21 proposal. 22 members of the CFTA at that time also conduct 22 Q Okay. Isn't it true that none of these 23 23 studies were done because PCPC and its members their own study? 24 A I'm not recalling specifically which 24 just didn't want to know the results? 25 document you're talking about. 25 MR. LOCKE: Objection. Page 649 Page 651 1 Q Okay. Do you -- as you sit here today, 1 THE WITNESS: No. I mean, we take the 2 do you recall that -- whether or not it was in a 2 direction of our members, and the members' reasons 3 document or not, do you recall that Dr. Wehner 3 for not funding would -- I mean, you would have to 4 made a recommendation to the CFTA to do its own 4 ask them. 5 study? 5 BY MR. GOLOMB: 6 A I'm not recalling that right now. 6 Q Okay. So sitting here today, you don't 7 Q And do you recall that in that letter 7 know why it is that Rothman, Wynder, Muscat and 8 back in 1994 that Dr. Wehner also told the CFTA 8 Wehner were all rejected, their proposals. Is 9 that it would be easy to do and that the results 9 that what you're telling us? 10 would be -- would come back within six months? Do 10 MR. LOCKE: Objection. 11 you recall that? Does that help refresh your 11 THE WITNESS: I think the only thing I 12 recollection? 12 could say would be the Rothman one, because that's 13 A Can you -- can you show me the document, 13 one thing we looked at, and we knew that -- again, because I'm not sure what study you're talking 14 14 it's not all costs, but we were hoping for just a 15 about. 15 reasonable, normal cost, and that I think -- I'm 16 Q Okay. Do --16 sure we would have gone ahead, but it was in a A Can you tell me what kind of study 17 17 ballpark that was just not rational. 18 BY MR. GOLOMB: 18 he's -- he's --19 Q Do you recall Dr. Wehner recommending 19 Q Okay. And that ballpark was \$100,000? 20 any kind of study? 20 MR. LOCKE: Objection. 21 THE WITNESS: That -- that's my 21 A Well, I mean, he did a study for us, and 22 he did various assessments of the data, but I 22 recollection, yes. 23 think you're talking about something real 23 BY MR. GOLOMB: 24 24 Q All right. And you are aware, are you specific, and I --25 Q Do you recall Dr. Wehner recommending a 25 not, that -- that before that decision was made,

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Page 652 Page 654 Citizen Petition. 1 that Dr. Cramer had published on the association 1 2 between talc and ovarian cancer, correct? 2 Q Which one? 3 A In 1982, yes. 3 A The 2008, so the 2009 response. 4 Q Right. He also published in 1992. 4 Q So as far as you know, Dr. Huncharek did 5 A I know he published -- he was a coauthor 5 not do any work for PCPC before 2008? 6 on the Gertig paper. 6 A I'm just trying to think and make sure 7 Q Right. And in that paper, in a footnote 7 I'm not skipping anything. I think that's 8 8 in that paper he talks about the -- the numbers of correct. 9 women who died from ovarian cancer. Do you recall 9 Q Okay. And how was it that Dr. Huncharek 10 that? 10 was retained by PCPC or one of its members? 11 A I do not. 11 A Again, it was --Q All right. Tell me if this sounds MR. LOCKE: Objection. 12 12 13 familiar: 22,000 women a year had ovarian cancer. 13 THE WITNESS: -- J&J that reached out to Does that sound familiar? 14 14 him first. And they were familiar with him from 15 A That sounds like what I heard this 15 various work. 16 16 BY MR. GOLOMB: morning too. 17 Q Okay. And 14,000 women a year die from 17 Q Who was it at J&J? 18 ovarian cancer. Does that sound familiar? 18 A Who did I talk to at J&J at the time? I 19 19 A That sounds about a number I would don't remember. expect from the --20 20 Q Okay. So in the -- in the deposition 21 Q Okay. And in Dr. Cramer's paper in 21 notice -- and I hate to tell you we're still on 22 1992, he concludes that 10 percent of those women 22 topic 1, there's only 17 more to go -- but it die from a -- from talc and ovarian cancer. 23 refers to the Weinberg Group. Do you know who the 23 24 MR. LOCKE: Object --24 Weinberg Group is? 25 BY MR. GOLOMB: 25 A Yes. Page 653 Page 655 1 Q Do you recall that in the paper? 1 Q And who is the Weinberg Group? 2 MR. LOCKE: Objection. Mischaracterizes 2 A Weinberg Group is a consulting group, 3 3 and we hired them at the time of the NTP report to the paper. 4 BY MR. GOLOMB: 4 pull together a binder, organize all the 5 5 information, and then reach out to consulting Q Do you recall that? 6 A I -- I recall something along those 6 epidemiologists. 7 lines. It doesn't mean we agreed with that, 7 Q All right. And that was in 1999, 2000? 8 8 though. A It was in 2000. 9 9 Q All right. And was -- did anybody from Q No, I understand. But that's -- that 10 is what was reported in 1992 before the decision 10 the Weinberg Group talk to Dr. Huncharek at that time, do you know? 11 was made not to do a study that was recommended 11 12 by Dr. Rothman, Dr. Wynder, Dr. Muscat and 12 A Not that I'm aware of. 13 Dr. Wehner? 13 Q Who did they talk to? 14 14 A The people that were hired through the MR. LOCKE: Objection. 15 THE WITNESS: I mean, I -- if that's 15 Weinberg Group were Drs. Rothman, Pastides, and 16 what was said in the paper, again, I don't -- I 16 Samet, Dr. Samuel Shapiro, and Dr. Muscat. 17 would have to look back, and we didn't agree with 17 Q All right. And they are -- some or all of them were the ones who then wrote the report 18 18 19 BY MR. GOLOMB: 19 that was then submitted to the NTP? 20 20 Q All right. So let me ask you about A There were three separate reports, and, 21 Dr. Huncharek, and I'm not going to go through the 21 yes, those are the authors. Three of them on one 22 study again. Mr. Tisi did that well. 22 and then individuals from Muscat and Shapiro. 23 When -- when did PCPC first retain 23 Q All right. And then somebody actually 24 Dr. Huncharek for any reason? 24 made the report to the NTP, correct? 25 A I believe it was for the answer to the 25 A Correct.

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Page 656 Page 658 1 MR. LOCKE: Objection. This material 1 BY MR. GOLOMB: 2 was covered at length by Mr. Meadows. These 2 Q Okay. That was an answer? 3 questions have been asked and answered. 3 A Yeah, I think they work on our website. 4 MR. GOLOMB: I don't -- I'm not sure if 4 I think they work on putting messages together, 5 5 and they work with our Public Affairs people. that's true or not, but I -- I don't -- I only 6 have a couple of minutes on this, so it's not 6 Q Well, my question was who is 7 going to take much time. 7 Burson-Marsteller? 8 THE WITNESS: Dr. Rothman made a 8 A It's a company. 9 presentation on -- on that that there -- the 9 Q It's a company. All right. And is that 10 something you learned in your preparation for 10 report that the three of them put together, the 11 review that the three of them put together. 11 today's deposition? A I had heard of them, the name before. 12 BY MR. GOLOMB: 12 13 Q Okay. And it was -- you're saying --13 Q All right. Who is Nichols-Dezenhall? 14 A So Dr. Pastides, not Dr. Rothman. A Nichols-Dezenhall is a public affairs 14 15 Q Okay. It was not Dr. Rothman, correct? 15 company that did work for CTFA back some many A That's correct, it was Dr. Pastides. 16 16 years ago. I'm not sure that we've used them at 17 17 Q In fact, you recall in your review of all in recent years. They did a couple of focus groups around the time of the NTP report on talc. 18 the documents that Dr. Rothman was kind of upset 18 19 that he wasn't able to make the presentation? Do 19 We use them I know for other things. 20 Q When did you learn about the focus 20 you recall that? 21 A Not really. 21 groups? 22 Q Okay. Burson-Marsteller, who is that? 22 A In my preparation for this deposition. A I think they're a -- I think they do 23 Q Okay. Because you recall -- I was the 23 24 work for PCPC on our website or on our -- perhaps 24 one who asked you about Nichols-Dezenhall before, 25 on cosmeticsinfo.org. I think --25 do you remember that? Page 657 Page 659 1 Q I'm sorry? 1 MR. LOCKE: When you say "before," what 2 A Perhaps on cosmeticsinfo.org. 2 do you mean? 3 Q Who -- who are they? 3 THE WITNESS: Yeah. A I think they're people that help prepare 4 4 BY MR. GOLOMB: 5 information, and they work with our Public Affairs 5 Q In your prior deposition in July of 6 department. 6 2018. 7 7 Q Okay. A I -- I couldn't recall who it was, but I 8 A I think. 8 do remember being asked about that, and I gave an 9 Q And so you're -- you're looking like you 9 answer that was not quite accurate, and that's why 10 don't know too much about them. 10 I made sure I was clarified on that after the 11 A I don't know too much about them. 11 12 Q All right. Did you -- you reviewed 12 Q All right. So did you review your -the -- the notice of deposition before you your deposition transcript from 2018 to help 13 13 14 testified? 14 prepare you today? 15 A Yes. 15 A I -- I read over it to see if there were 16 Q And so you know under 1(f), it 16 any things that I was confused about and made sure specifically says that we're going to ask 17 17 I had answers -- my answers correct. questions about Burson-Marsteller? 18 Q And I deposed you in -- I think it was 18 19 2016 as well, correct? A Yes. 19 20 20 Q Okay. So did you prepare yourself to A That's correct. 21 21 answer questions about Burson-Marsteller? Q Did you review that in preparation for 22 MR. LOCKE: Why don't you ask her a 22 your deposition today? 23 question about them. 23 A Not today, no. 24 24 Q I also after your deposition in July of MR. GOLOMB: Well, I did. 25 MR. LOCKE: And she answered. 25 2018 and before today deposed Mr. Pollack. You

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	Page 660		Page 662
1	know him, correct?	1	52418.
2	A Yes.	2	Which is part of the same composite,
3	Q And just for the ladies and gentlemen of	3	correct?
4	the jury, can you explain who Mr. Pollack is.	4	A Yes, so it appears.
5	A Mark Pollack is I should know his	5	Q And it says: "Mission accomplished by
6	title, but he is an employee of the Personal Care	6	promoting," and then the first bullet point says:
7	Products Council. He reports directly to our CEO.	7	"Voluntary industry self-regulation."
8	He has an executive VP title. Perhaps it's for	8	Is that still a primary mission of PCPC?
9	membership. I'm not sure.	9	A I guess I would probably say no in the
10	Q Okay. And did you read Mr. Pollack's	10	fact that we have been working on getting updated
11	deposition transcript?	11	regulations passed for the cosmetic industry for
12	A I did not.	12	the past 12 years.
13	Q All right. Can we go to document 50	13	Q Well, let's go to the next document,
14	52415.	14	which is PCPC 52424.
15	This was a composite document. Which	15	And it says at the top "Self-regulation
16	has been marked as Exhibit 70.	16	Programs," and under the first bullet point it
17	(Exhibit No. 70 was marked for	17	says "CIR," correct?
18	identification.)	18	A Yes.
19	BY MR. GOLOMB:	19	Q All right. And CIR is still a
20	Q To me it appears to be a it's a PCPC	20	self-regulatory program that is funded by the
21	document, and to me it appears to be a PowerPoint	21	PCPC, correct?
22	of some sort.	22	A It is still funded by the PCPC, correct.
23	Have you seen this before?	23	Q And it's still a self-regulatory
24	A I may have seen it in my preparation.	24	program, correct?
25	I'm not sure.	25	A I guess you could call it that. I mean,
	Page 661	23	Page 663
1	Q Okay. Can you tell us what it is?	1	we we undertook CIR because FDA didn't. So
2	A Well, it looks like it's kind of an	2	Q The next document in that same
3	introduction to what is what is CTFA.	3	PowerPoint is PCPC 52426.
4	Obviously, this is older since we're now PCPC.	4	Do you see that?
5	MR. LOCKE: And just for the record, I	5	A Yes.
6	want to note it's missing quite a few pages, and	6	Q And it basically is talking about the
7	some pages well	7	the trade association obviously being at that time
8	MR. TISI: Right. And for the record,	8	CTFA, now PCPC, and some of the the member
9	,		CITA, now i Ci C, and some of the the member
)		ıu	samilage garragt?
1.0	it was about a 50-page document, and the ones I	9	services, correct?
10	made copies of are the ones I'm asking questions	10	A Yes.
11	made copies of are the ones I'm asking questions about.	10 11	A Yes. Q And the first bullet point provides
11 12	made copies of are the ones I'm asking questions about. BY MR. GOLOMB:	10 11 12	A Yes. Q And the first bullet point provides current information?
11 12 13	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review	10 11 12 13	A Yes. Q And the first bullet point provides current information? A Yes.
11 12 13 14	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was	10 11 12 13 14	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources,
11 12 13 14 15	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?	10 11 12 13 14 15	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as
11 12 13 14 15 16	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that	10 11 12 13 14 15	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force.
11 12 13 14 15 16 17	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.	10 11 12 13 14 15 16	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes.
11 12 13 14 15 16 17	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC?	10 11 12 13 14 15 16 17	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection.
11 12 13 14 15 16 17 18	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC?  A Roughly 2006.	10 11 12 13 14 15 16 17 18	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection. BY MR. GOLOMB:
11 12 13 14 15 16 17 18 19 20	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC?  A Roughly 2006.  Q Now, did you ever see this document	10 11 12 13 14 15 16 17 18 19 20	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection. BY MR. GOLOMB: Q And then the third bullet point is
11 12 13 14 15 16 17 18 19 20 21	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC?  A Roughly 2006.  Q Now, did you ever see this document before you were preparing for this deposition?	10 11 12 13 14 15 16 17 18 19 20 21	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection. BY MR. GOLOMB: Q And then the third bullet point is allows you to influence industry policy and
11 12 13 14 15 16 17 18 19 20 21 22	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC? A Roughly 2006. Q Now, did you ever see this document before you were preparing for this deposition? A I doubt it.	10 11 12 13 14 15 16 17 18 19 20 21 22	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection. BY MR. GOLOMB: Q And then the third bullet point is allows you to influence industry policy and action. Correct?
11 12 13 14 15 16 17 18 19 20 21 22 23	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC?  A Roughly 2006.  Q Now, did you ever see this document before you were preparing for this deposition?  A I doubt it.  Q So do you know who prepared it?	10 11 12 13 14 15 16 17 18 19 20 21 22 23	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection. BY MR. GOLOMB: Q And then the third bullet point is allows you to influence industry policy and action. Correct? A Yes.
11 12 13 14 15 16 17 18 19 20 21 22	made copies of are the ones I'm asking questions about.  BY MR. GOLOMB:  Q Is there anything, based on your review of those documents, that can tell us when this was used?  A No. That's to say, only from CTFA that tells you something.  Q Right. So when did CTFA change to PCPC? A Roughly 2006. Q Now, did you ever see this document before you were preparing for this deposition? A I doubt it.	10 11 12 13 14 15 16 17 18 19 20 21 22	A Yes. Q And the first bullet point provides current information? A Yes. Q The second extends your resources, meaning that you can pull your resources like as in a task force. A That's one way, yes. MR. LOCKE: Objection. BY MR. GOLOMB: Q And then the third bullet point is allows you to influence industry policy and action. Correct?

72 (Pages 660 to 663)

Page 664 Page 666 1 A That's what it says. 1 clearance required. 2 Q Right. So meaning that PCPC, or at that 2 A There's no premarket approval, that's 3 time CFTA, kind of acted as the intermediary to 3 correct. 4 deal with the government confrontation? 4 Q As opposed to a pharmaceutical which 5 5 A For example, comments where the does. 6 companies would -- where we would coordinate 6 A That the active ingredients would be 7 and -- and we would submit comments. 7 approved, yes. 8 8 Q Right. Cosmetics have less rigorous Q Correct. Or as in this case, where 9 the -- the CFTA would put its name on a document 9 inspections --10 so that J -- J&J didn't have to. 10 A Yes. 11 MR. LOCKE: Objection. 11 Q -- than a pharmaceutical. THE WITNESS: We were -- we were the And cosmetics have no specific standards 12 12 13 face of -- we were serving as the face of the 13 for efficacy. 14 industry. 14 A Well, cosmetics don't have efficacy the BY MR. GOLOMB: 15 same way that drugs do, so that just kind of 15 16 Q Right. And in this case, though, you 16 17 were serving as the face of the industry at the 17 Q Correct. That's part of the 18 specific request of J&J, who said -- who basically 18 self-regulatory standard. 19 concurred with the report that they reviewed, but A No, I mean, cosmetics are not -- they 19 suggested that it shouldn't be their name on it, 20 20 don't affect the structure or function of the 21 it should be your name on it, correct? 21 body. That's by definition. So they don't have 22 MR. LOCKE: Objection. 22 efficacy in a way that a drug would. THE WITNESS: We had to agree with the Q Let's turn to 52505. 23 23 Well, that's it, but it's upside down on 24 report as well. 24 25 BY MR. GOLOMB: 25 the screen. There you go. Page 665 Page 667 1 Q All right. But that's to allow them to 1 So when this describes expert panels, it avoid direct company-government confrontation, 2 2 talks about liaison members, and I assume, correct 3 correct? 3 me if I'm wrong, this is liaisoned from the -- at 4 4 MR. LOCKE: Objection. the time the CFTA to various governmental 5 THE WITNESS: I'm not sure that would be 5 agencies, correct? 6 confrontation, but -- but, yes, we were the face 6 MR. LOCKE: Objection. 7 7 of the industry. THE WITNESS: I'm sorry. These are --8 8 yeah, there's three liaison members that still BY MR. GOLOMB: 9 Q All right. And the next document is 9 exist today. One is from FDA, one is from 10 10 Consumer Federation of America, and one is 52457. 11 This is essentially kind of describes 11 representing industry. 12 the differences, does it not, between cosmetic and 12 BY MR. GOLOMB: 13 the pharmaceutical? 13 Q Right. And these -- and so there was a 14 A In some ways, yes. And I have to say 14 lot of talk about John Bailey today. this -- this is out of date. I mean, we would not 15 15 16 produce something like this today. 16 Q So this is at a time when John Bailey Q But it's still holds true, though. You was still at the FDA, correct? 17 17 18 may not produce it, but it still holds true. 18 A Correct. 19 A Well, but -- no, what I'm saying is, for 19 Q And I want to understand the timeline of 20 example, in this legislation that we are 20 this. So with -- specifically with John Bailey. 21 advocating for -- good manufacturing practices are 21 The -- the first Citizens Petition was 22 a part of that, just as an example. So things 22 in 1993, correct? 23 change. 23 A Yes. 24 24 Q But one -- one of the things that still Q And that was at a time that John Bailey 25 holds true is that cosmetics have no prior FDA 25 was at the FDA, correct?

73 (Pages 664 to 667)

	Page 668		Page 670
1	A Yes.	1	A Correct.
2	Q And as as we saw from the letter,	2	Q to the CFTA or the PCPC.
3	John Bailey at some point, representing the FDA,	3	A Correct.
4	wrote a letter not rejecting the Citizens Petition	4	Q And that was after after he came to
5	but, rather, saying they didn't have the resources	5	the PCPC, and Bailey set up the meeting with the
6	to deal with it at that time, correct?	6	FDA, correct?
7	A I think that was just the initial	7	MR. LOCKE: Objection. Asked and
8	response.	8	answered.
9	Q The initial response in 1993, that's	9	THE WITNESS: Right. When he came to
10	what I'm talking about.	10	the he eventually set up the meeting in 2009.
11	A Right, which is but that's I mean,	11	BY MR. GOLOMB:
12	that's how they respond to Citizens Petitions	12	Q Right. And after he set up the meeting
13	initially, I think almost always.	13	with his old subordinates, that's when the the
14	Q I'm not I'm not questioning it one	14	Citizens Petition was rejected, correct?
15	way or the other. I'm just trying to understand	15	MR. LOCKE: Objection.
16	the timeline.	16	THE WITNESS: I think there were other
17	A He wrote that initial letter in	17	things that went on in the meantime. For example,
18	response, yes.	18	the assessment of the talcs admittedly not
19	Q Right. When he was when he was at	19	exhaustive, but the assessment of talcs for
20	the FDA.	20	asbestos.
21	A At FDA, Yes.	21	BY MR. GOLOMB:
22	Q And then he gets hired by the CFTA when?	22	Q Well, but at that point in 2008, there
23	A Okay. Let's see. I started in '97.	23	had been 24 or more studies that already looked at
24	It's like 2000 and let's see. He took my	24	the association between talc and ovarian cancer,
25	boss old boss's job in 2000 and	25	and something like 18 of those studies showed a
	Page 669		Page 671
1	Q If you can speak up so that the	1	statistically significant association between talc
2	A I'm just ruminating instead of silence.	2	and ovarian cancer, correct?
3	Q Yeah, I know, but if you're going to	3	MR. LOCKE: Objection.
4	ruminate out loud, you have to say it so the court	4	THE WITNESS: I would say there were
5	reporter can get it.	5	it's it's much more it's more complex than
6	A Just trying to figure out it would	6	that. I mean, there were other issues, as have
7	have been roughly 2003, '2.	7	been pointed out, of biologic plausibility, of
8	Q Okay. And between 1993 and 2002 or	8	dose-response. So it's a little not as
9	2003, when Bailey came from the FDA to the CFTA,		
	2005, when baney came from the FDA to the CFTA,	9	straightforward as that.
10	there had been no response to the Citizens	9   10	
10 11			straightforward as that.
	there had been no response to the Citizens	10	straightforward as that. BY MR. GOLOMB:
11	there had been no response to the Citizens Petition other than, We don't have the resources,	10 11	straightforward as that.  BY MR. GOLOMB:  Q Well, understood. I mean, we we I
11 12	there had been no response to the Citizens Petition other than, We don't have the resources, correct?	10 11 12	straightforward as that.  BY MR. GOLOMB:  Q Well, understood. I mean, we we I think we can agree that during this period of time
11 12 13	there had been no response to the Citizens Petition other than, We don't have the resources, correct? MR. LOCKE: Objection.	10 11 12 13	straightforward as that.  BY MR. GOLOMB:  Q Well, understood. I mean, we we I think we can agree that during this period of time between, you know, 1982 and 2008, that while there
11 12 13 14	there had been no response to the Citizens Petition other than, We don't have the resources, correct?  MR. LOCKE: Objection. THE WITNESS: I thought there was a	10 11 12 13 14	straightforward as that.  BY MR. GOLOMB:  Q Well, understood. I mean, we we I think we can agree that during this period of time between, you know, 1982 and 2008, that while there were all these other studies that were coming out,
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11 12 13 14 15 16 17 18 19 20 21 22	there had been no response to the Citizens Petition other than, We don't have the resources, correct?  MR. LOCKE: Objection.  THE WITNESS: I thought there was a response.  BY MR. GOLOMB:  Q And what was the response?  A I thought the initial one was rejected.  Q Okay. And is that something you saw today?  A No, I haven't seen it today. We just saw the latter one today, the 2008, that was	10 11 12 13 14 15 16 17 18 19 20 21	straightforward as that.  BY MR. GOLOMB:  Q Well, understood. I mean, we we I think we can agree that during this period of time between, you know, 1982 and 2008, that while there were all these other studies that were coming out, more than two dozen studies, most of which showed the statistically significant association, while at the same time Johnson & Johnson and the PCPC were rejecting case controlled studies of their own, but at that during that period of time, industry chose, rather than doing its own study, to do a critical analysis of the individual studies, correct?

74 (Pages 668 to 671)

Page 672 Page 674 1 THE WITNESS: Yeah, we don't -- PCPC 1 BY MR. GOLOMB: 2 Q And -- but did not do its own study. 2 does not get into labeling. 3 3 A We did not do an epidemiology study. BY MR. GOLOMB: 4 Q Mr. Tisi asked you before about the 4 Q Right. And as far as you know, the FDA standard, and I've asked you about this before, so 5 also doesn't tell a company what to put on a 5 б I'm not going to go into a lot of detail about it. 6 label, correct? 7 But it's a document which was previously 7 MR. LOCKE: Objection. Beyond the 8 marked for identification as Plaintiff's Exhibit 8 scope. 9 9 324 ---THE WITNESS: I mean, the FDA opined on 10 MR. GOLOMB: Okay. That's fine. 10 the Citizens Petitions. 11 -- which we will mark as Exhibit 71. 11 BY MR. GOLOMB: 12 (Exhibit No. 71 was marked for 12 Q Well, but they don't tell the company 13 identification.) 13 when -- when to put a label on and when not to, 14 BY MR. GOLOMB: 14 Q All right. This is the Code of Federal MR. LOCKE: Objection. Beyond the 15 15 16 Regulations, Title 21. Are you familiar with 16 scope. 17 this? 17 THE WITNESS: I really don't know. 18 18 BY MR. GOLOMB: A Yes. Q All right. Did you at any time in 19 Q Were you aware of this before I asked 19 preparation for any of these depositions read the 20 you about it? 20 21 A I -- I'm not familiar with specifically 21 testimony of Dr. Bailey? 22 these labeling requirements, and we don't get into 22 A I did not. issues of labeling beyond telling our -- helping 23 Q Okay. Were you aware that Dr. Bailey 2.3 24 our companies understand what current labeling 24 has testified not in a -- in an ovarian cancer 25 requirements are in our labeling manual. 25 case, but in an asbestos case where he discussed Page 673 Page 675 1 Q Okay. But I -- I've asked you about 1 very specifically the role of the FDA in this before, correct? Do you recall that? 2 2 cosmetics? 3 A I -- I -- I don't recall specifically. 3 MR. LOCKE: Objection. Q All right. This is the Code of Federal 4 4 You can answer. 5 Regulations, Title 21, Section 740.1, 5 THE WITNESS: I mean, I knew he 6 "Establishment of Warning Statements." 6 testified. I don't know any specifics beyond 7 7 Did I read that correctly? that. 8 8 A Yes. BY MR. GOLOMB: 9 Q And can you just read subsection (a) for 9 Q All right. I want to move to topic 7, 10 10 which is the National Cancer Institute. the jury, please. 11 A "The label of a cosmetic product shall 11 What is the National Cancer Institute? 12 bear a warning statement whenever necessary or 12 A It's a governmental agency. I'm not 13 appropriate to prevent a health hazard that may be 13 sure "agency" is the right word. It's a 14 associated with the product." 14 governmental body that I believe funds cancer 15 15 Q "That may be associated with the research. 16 product," correct? 16 Q And what -- what, if any, communications, directly or indirectly, does the 17 A That's what it says. 17 18 Q All right. And that is a determination PCPC have with the NCI generally? 18 of whether or not a company is going to label a A I'm not aware of any. 19 19 20 cosmetic product with a warning statement. That 20 Q At any time? 21 is a decision to be made by the company, correct? 21 A I'm not aware of any, no, at any time. 22 A That's --22 Q All right. Have you ever -- and I'm 23 MR. LOCKE: Objection. 23 not -- when I say "you," I'm talking about anybody 24 THE WITNESS: That's not something --24 at PCPC because that's your role here today --MR. LOCKE: Beyond the scope. 25 25 A Yes.

75 (Pages 672 to 675)

Page 676 Page 678 1 Q -- to testify on behalf of PCPC. 1 A I wouldn't have because I am absolutely 2 Have you had any contact with a member 2 certain they would not do that without talking to 3 3 organization, be it J&J, Luzenac, Rio Tinto, the Science department. 4 Imerys, or any other member, where you have 4 Q And why do you say that? A Because that's just the way we work. I 5 learned that they've had contact with the NCI? 5 6 A Not that I'm aware of. mean, when -- when the Public Affairs, for б 7 Q So when the NCI on a number of occasions 7 example, is doing any kind of a science issue, 8 8 on their website identifies talc as a risk of they're consulting with us. They're not doing 9 ovarian cancer, and then that was taken off the 9 that on their own. Q Let's go to the next document, which 10 website, you have no idea why? 10 11 A Correct. 11 we'll mark as Exhibit 72. 12 MR. LOCKE: Objection. 12 (Exhibit No. 72 was marked for 13 BY MR. GOLOMB: 13 identification.) Q Okay. Were you -- were you aware of 14 BY MR. GOLOMB: 14 that before I just told you that? 15 15 Q And this again is --16 A I was, and I can't remember how I became (Counsel conferring.) 16 17 aware of that. I'm not sure I was ever aware that 17 BY MR. GOLOMB: 18 18 Q Yeah, it's been previously marked for it was on. I was maybe aware that it was off. 19 identification as P-72. It's up on the screen. But I -- I don't recall --19 20 Q Have you ever --20 (Counsel conferring.) 21 A -- when I learned that. 21 BY MR. GOLOMB: 22 Q I'm sorry. I didn't mean to interrupt. 22 Q Now, this was the NCI website as of 23 A Oh, no, since I don't -- I'm not aware 23 September 15th, 2011. You can see that from the 24 of when I learned that. I mean, I just can't 24 lower right-hand corner. Do you see that? 25 25 A Yes. remember. Page 677 Page 679 1 Q Okay. Have you ever looked at the NCI 1 Q And this is the "Ovarian Cancer 2 website for any reason? 2 Prevention, PDQ, Prevention Patient Information." 3 A I think I looked at that having heard 3 Do you see that? 4 about that. 4 A Yes. 5 Q Well, you have a -- my word, not 5 Q Now, are you familiar with the PDQ? 6 yours -- I know we have previously gone through 6 A Um --7 the organizational chart in great detail, and 7 Q Not this one in particular. A PDQ 8 there was a Public Relations/Communications 8 generally. 9 9 A I'm trying to -- I'm not sure I know department, correct? 10 10 what it stands for. I think, again, because I've A On -- on our website? Q On PCPC. 11 seen something along these lines, I --11 12 A We have -- yes. 12 Q It's a Physician's Data Query. 13 Q Right. And in preparation for this 13 A Okay. 14 deposition, you were asked very specifically about 14 O Does that sound familiar? 15 communications, directly or indirectly, with the 15 A Yeah, it does now. Yeah. 16 NCI concerning the risk of ovarian cancer caused 16 Q Okay. And so in order to go on to the website and go specifically to the PDQ, you have 17 by application of talcum powder. 17 A Okay. Yes. to be a physician or scientist that has access. 18 18 Is that consistent with your understanding? 19 Q And so in your role as a 30(b)(6) 19 20 witness, did you go to any of the employees within MR. LOCKE: Objection. Beyond the 20 21 the Communications department, Public Relations 21 scope. 22 department, whatever you call it, as well as 22 THE WITNESS: Yeah, I just wouldn't have 23 the -- the -- and again my word, not yours -- the 23 known that. 24 lobbying arm of PCPC to find out if they had any 24 BY MR. GOLOMB: 25 communications with the NCI? 25 Q Okay. And that's fine, by the way. If

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the NCI as of September 5th, 2011, correct?  A Right I don't know.  Q So that if a – a woman who has ovarian cancer and is claiming that she got her ovarian cancer from the use of talcump powder, she would not, unless she was a physician or a scientist, have access to the PDQ. Is that consistent with your understanding?  MR LOCKE: Objection. Beyond the scope.  THE WITNESS: September 15th, but yes.  BY MR. GOLOMB:  THE WITNESS: I think only just from what you just said, that access is limited to 12 document, which is MBS-CRE271.  Eshibit No. 73 was marked for identification.)  BY MR. GOLOMB:  O Chay. Well, on the other hand, if anybody went on to the NCI website, and in the scarch box typed in "ovarian cancer," they would get a – a Snapshot of Ovarian Cancer. Is that consistent with your understanding?  MR. LOCKE: Objection. Beyond the scope.  What you understanding the state of this search box typed in "ovarian cancer," they would get a – a Snapshot of Ovarian Cancer. Is that consistent with your understanding?  MR. LOCKE: Objection. Beyond the scope.  Q Okay. Now, let's go to the next document, which is MBS-CRE271.  (Eshibit No. 73 was marked for identification.)  BY MR. GOLOMB:  A Yes.  A Yes.  A Yes.  A Yes.  A Yes.  A Correct.  A He is with the CRB.  A Page 683  A Correct.  A He is with the CRB.  A Page 1 of 2, from Jim Tozzi to Bill Kelly. Jr.?  A He is with the CRB.  A Page 1 of 2, from Jim Tozzi to Bill Kelly. Jr.  A Pagin and the anus, may reach the ovaries by entering the vagina.'  A That's what it says, yes.  A That's what it says, yes.  A Correct.  A Correct.  A Correct.  A Correct.  A Correct.  A Page 683  A Correct.  A Page 683  A Correct.  A Correct.  A Page 683  A Correct.  A Page 684  BY MR. GOLOMB:  Correct. And that was to 9 or hard down late and		Page 680		Page 682
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the With With Yilliam Kelly, Jr., and Jim Tozzi, Page 683  The With Was it 72? — if you take a look at Exhibit 72 — 3 A Okay.  Exhibit — what was it 72? — if you take a look at Exhibit 72 — 3 A Okay.  MR. LOCKE: Just to be clear, it's pages 1 and 3 of a seven-page document. MR. GOLOMB: Correct. And that was to show the cover page and the portions relevant to take.  MR. GOLOMB: Q Have you seen that before?  A Isaw it in preparation for this. Q Okay. Do you need time to review it now or —  A Yes. Q Go ahead. Q This is an e-mail exchange back in April of 201 between William Kelly, Jr., and Jim Tozzi, correct?  Page 681  Exhibit — what was it 72? — if you take a look at Exhibit 72 — 2 A A look with CRE, I believe.  MR. LOCKE: Just to be clear, it's pages 1 and 3 of a seven-page document. MR. GOLOMB: Correct. And that was to show the cover page and the portions relevant to take.  MR. GOLOMB: Or or are you familiar with it?  A Correct.  A Correct. Q Who is William Kelly, Jr., and Jim Tozzi, or or exity in the CRE. A Also with CRE, I believe. Q And if you look at the middle e-mail on page 1 of 2, from Jim Tozzi to Bill Kelly. April 15th, 2013, at 11:12 a.m. Do you see that? A Yes. Q Is ays — the second — the last line on that e-mail says: "Showing that the CIR as unbiased and cleaning up material on the internet is critical if they are going to calm down lawsuits."  A That's what it says. Q Doyou see that? A That's what it says. Q Doyou show what he's referring to when he says "cleaning up material on the internet"? MR. LOCKE: Objection. Beyond the scope. A Pers. A Yes. Q And it says. "The use of tale may increase the risk of ovarian cancer. Talcum powder dusted on the perineum, the area between the vagina and the anus, may reach the ovaries by entering the vagina." Do you see that? A That's what it says, yes. Q Did I read that correctly?  A That's what it says, yes. Q Did I read that correctly?		· · ·		- · · · · · · · · · · · · · · · · · · ·
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20 entering the vagina." 20 THE WITNESS: I don't. We didn't see 21 Do you see that? 21 this. We never talked to them about this. 22 A That's what it says, yes. 23 Q Did I read that correctly? 20 THE WITNESS: I don't. We didn't see 21 this. We never talked to them about this. 22 BY MR. GOLOMB: 23 Q And do you know what he means by "calm"		= -		· · · · · · · · · · · · · · · · · · ·
21 Do you see that? 22 A That's what it says, yes. 23 Q Did I read that correctly? 21 this. We never talked to them about this. 22 BY MR. GOLOMB: 23 Q And do you know what he means by "calm				=
22 A That's what it says, yes. 23 Q Did I read that correctly? 22 BY MR. GOLOMB: 23 Q And do you know what he means by "calm				
23 Q Did I read that correctly? 23 Q And do you know what he means by "calm				
	22			
44		Q Did I read that correctly?	23	Q And do you know what he means by "calm
25 Q So that was a posted on the PDQ of 25 MR. LOCKE: Same objection.		<ul><li>Q Did I read that correctly?</li><li>A Yes.</li></ul>	23	Q And do you know what he means by "calm down lawsuits"?

77 (Pages 680 to 683)

	Page 684		Page 686
1	THE WITNESS: I mean, obviously he is	1	assume because it's an unusual name, that's who he
2	referring to litigation, I presume. But	2	is talking about, yes.
3	BY MR. GOLOMB:	3	BY MR. GOLOMB:
4	Q Okay. Well, are you aware one way or	4	Q All right. And do you know do you
5	the other as to whether or not there was any	5	know Mr. Sharma?
6	litigation in which any of these companies were	6	A I may have been on a phone call with him
7	sued as a result of the the relationship	7	once or twice, but I don't know if I've met him.
8	between talc and ovarian cancer as of April 13	8	Q All right. Have you ever spoken to him
9	April 15th, 2013?	9	specifically about tale and its association with
10	MR. LOCKE: When you say "any of these	10	ovarian cancer?
11	companies," to whom are you referring?	11	A As I said, I may have been on a phone
12	MR. GOLOMB: J&J and Imerys and their	12	
	•	13	call, and I can't remember context, but I mean,
13	predecessors.		it'd be on a conference call. I don't believe
14	MR. LOCKE: Objection. Beyond the	14	I've ever spoken to him one on one.
15	scope.	15	Q All right. And if we look at the last
16	THE WITNESS: Yeah, I don't know the	16	sentence going on to the next, the first sentence
17	dates of lawsuits, and I I just don't know.	17	of the next page, it says: "Shripal knows that we
18	BY MR. GOLOMB:	18	engineered the CIR report from the outset."
19	Q Okay. The on the bottom of the page,	19	Did I read that correctly?
20	there's an e-mail from William Kelly, Jr., to	20	A That's what it says.
21	Tozzi on April 15th, 2013, just 24 minutes before,	21	Q And that's from one CRE employee to
22	at 12:48 p.m.	22	another?
23	Do you see that?	23	A That's what it looks like.
24	A Yes.	24	Q Let let's take a look at the next
25	Q And if we look at the second paragraph	25	document, which was previously marked for
	Page 685		Page 687
1	that begins: "The only account I am working on	1	identification as Plaintiff's Exhibit P-225.
2	currently is talc." Do you see that?	2	(Exhibit No. 74 was marked for
3	A Yes.	3	identification.)
4	Q And that is that's William Kelly, Jr.	4	BY MR. GOLOMB:
5	saying that, correct?	5	Q This is another Ovarian Cancer
6	A Yes.	6	Prevention PDQ, correct?
7	Q And in the it says: "The only	7	A Yes.
8	account I am working on currently is talc. Of	8	Q And you'll see on the bottom right-hand
9	course, I also want to write an article on the IQA	9	corner it's dated June 12, 2013.
10	_		2011c1 it b dated saile 12, 2013.
1 - 5	diffing the flext six months as well as clean in the	()	A Yes
11	during the next six months as well as clean up the Wikinedia entry on the IOA "	10	A Yes. O Approximately two years after the last
11	Wikipedia entry on the IQA."	11	Q Approximately two years after the last
12	Wikipedia entry on the IQA." What is the IQA?	11 12	Q Approximately two years after the last one I showed you.
12 13	Wikipedia entry on the IQA."  What is the IQA?  A I have	11 12 13	Q Approximately two years after the last one I showed you.  A Approximately.
12 13 14	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the	11 12 13 14	<ul><li>Q Approximately two years after the last one I showed you.</li><li>A Approximately.</li><li>Q And if you go on to the next page,</li></ul>
12 13 14 15	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.	11 12 13 14 15	Q Approximately two years after the last one I showed you.  A Approximately.  Q And if you go on to the next page, towards the bottom quarter of the page, it refers
12 13 14 15 16	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.	11 12 13 14 15	Q Approximately two years after the last one I showed you.  A Approximately.  Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct?
12 13 14 15 16 17	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:	11 12 13 14 15 16	Q Approximately two years after the last one I showed you.  A Approximately.  Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct?  A I only have page 1.
12 13 14 15 16 17 18	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named	11 12 13 14 15 16 17	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct? A I only have page 1. Q I'm going to hand you my copy and ask
12 13 14 15 16 17 18 19	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named Shripal. Do you see that?	11 12 13 14 15 16 17 18 19	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct?  A I only have page 1. Q I'm going to hand you my copy and ask you to turn to page 2.
12 13 14 15 16 17 18 19 20	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named Shripal. Do you see that?  A Yeah yes.	11 12 13 14 15 16 17 18 19 20	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct? A I only have page 1. Q I'm going to hand you my copy and ask you to turn to page 2. Do you see the highlighted area?
12 13 14 15 16 17 18 19 20 21	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named Shripal. Do you see that?  A Yeah yes.  Q Who is that?	11 12 13 14 15 16 17 18 19 20 21	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct? A I only have page 1. Q I'm going to hand you my copy and ask you to turn to page 2. Do you see the highlighted area? A Yes.
12 13 14 15 16 17 18 19 20 21 22	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named Shripal. Do you see that?  A Yeah yes.  Q Who is that?  A Shripal is somebody at Imerys.	11 12 13 14 15 16 17 18 19 20 21 22	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct? A I only have page 1. Q I'm going to hand you my copy and ask you to turn to page 2. Do you see the highlighted area? A Yes. Q Can you just read that for the jury,
12 13 14 15 16 17 18 19 20 21 22 23	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named Shripal. Do you see that?  A Yeah yes.  Q Who is that?  A Shripal is somebody at Imerys.  Q Right, that's Shripal Sharma, correct?	11 12 13 14 15 16 17 18 19 20 21 22 23	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct?  A I only have page 1. Q I'm going to hand you my copy and ask you to turn to page 2.  Do you see the highlighted area? A Yes. Q Can you just read that for the jury, please.
12 13 14 15 16 17 18 19 20 21 22	Wikipedia entry on the IQA."  What is the IQA?  A I have  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I don't know.  BY MR. GOLOMB:  Q And then it refers to somebody named Shripal. Do you see that?  A Yeah yes.  Q Who is that?  A Shripal is somebody at Imerys.	11 12 13 14 15 16 17 18 19 20 21 22	Q Approximately two years after the last one I showed you.  A Approximately. Q And if you go on to the next page, towards the bottom quarter of the page, it refers to talc, correct? A I only have page 1. Q I'm going to hand you my copy and ask you to turn to page 2. Do you see the highlighted area? A Yes. Q Can you just read that for the jury,

78 (Pages 684 to 687)

	Page 688		Page 690
1 p	owder dusted on the perineum, the area between	1	the vagina and the anus, may reach the ovaries by
_	he vagina and the anus, may reach the ovaries by	2	entering the vagina."
	entering the vagina."	3	Q Okay. Thank you.
4	Q Okay. And that was in June of 2013,	4	Let me show you the next document.
	ofter the first of the lawsuits in the in these	5	And this is a document which has been
	ases were filed. Are you aware of that?	6	previously marked for identification as P-385.
7	MR. LOCKE: Objection. Beyond the	7	(Exhibit No. 76 was marked for
	cope.	8	identification.)
9	THE WITNESS: I'm not aware of the	9	BY MR. GOLOMB:
	lates, no.	10	Q Have you seen this document before?
	BY MR. GOLOMB:	11	A Not that I know of, no.
12	Q Okay. Let me show you the next	12	Q All right. Now, you'll see at the
	locument, which has been marked as P-384.	13	bottom this document was dated March 19th, 2015.
14	(Exhibit No. 75 was marked for	14	Do you see that?
15	identification.)	15	A Yes.
	BY MR. GOLOMB:	16	Q And this is after the IARC report that
17	Q This is another Ovarian Cancer	17	came out and declared talc a Class 2B carcinogen,
	Prevention PDQ, correct?	18	correct?
19	A Yes.	19	MS. FRAZIER: Object to form.
20	Q All right. And this is a little bit	20	MR. LOCKE: Objection. I'm not going to
	lifferent format taken from the website than	21	direct the witness not to answer, but she's
	previous ones, correct?	22	testified she has not seen these exhibits
23	A Yes.	23	previously. I'm there's a lack of foundation.
24	Q And do you see the the date of this	24	It's beyond the scope.
25 ii	n the bottom of the page?	25	You can answer to the extent you can.
	Page 689		Page 691
1	A It's hard to read, but it's, I think,	1	THE WITNESS: And so what was the
	August 18, 2014.	2	question?
3	Q And at the top of the page, it says:	3	BY MR. GOLOMB:
	The following risk factors may increase the risk	4	Q This document is dated March 19th,
	of ovarian cancer." Do you see that?	5	2015
6	A I do.	6	A Correct.
7	Q And the the fifth risk factor there	7	Q which is after the IARC report came
8 is	s what?	8	out, correct?
9	A It says	9	A Yes.
10	MR. LOCKE: Objection. Beyond the	10	
			Q The IARC report which announced that
	ž ž	11	1
12 E	cope.	11 12	the they concluded that talc was a Class 2B
12 E	cope. BY MR. GOLOMB:		the they concluded that talc was a Class 2B carcinogen, correct?
	cope. BY MR. GOLOMB: Q Is what?	12	the they concluded that talc was a Class 2B
13	cope. BY MR. GOLOMB: Q Is what? A It says "talc."	12 13	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.
13 14 15	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3,	12 13 14	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence.
13 14 15	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct?	12 13 14 15	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:
13 14 15 16 it	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3,	12 13 14 15 16	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer
13 14 15 16 it	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct? MR. LOCKE: Objection. Beyond the	12 13 14 15 16 17	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer Prevention PDQ that we're now referring to refers
13 14 15 16 it 17 18 s	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct? MR. LOCKE: Objection. Beyond the cope.	12 13 14 15 16 17 18	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer Prevention PDQ that we're now referring to refers to the IARC report, correct?
13 14 15 16 it 17 18 s	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct? MR. LOCKE: Objection. Beyond the cope. THE WITNESS: Yes.	12 13 14 15 16 17 18	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer Prevention PDQ that we're now referring to refers to the IARC report, correct?  MR. LOCKE: Objection.
13 14 15 16 it 17 18 s 19 20 E	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct? MR. LOCKE: Objection. Beyond the cope. THE WITNESS: Yes. BY MR. GOLOMB:	12 13 14 15 16 17 18 19 20	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer Prevention PDQ that we're now referring to refers to the IARC report, correct?  MR. LOCKE: Objection.  THE WITNESS: Yes.
13 14 15 16 it 17 18 s 19 20 E	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct? MR. LOCKE: Objection. Beyond the cope. THE WITNESS: Yes. BY MR. GOLOMB: Q And can you just read that for the jury,	12 13 14 15 16 17 18 19 20 21	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer Prevention PDQ that we're now referring to refers to the IARC report, correct?  MR. LOCKE: Objection.  THE WITNESS: Yes. BY MR. GOLOMB:
13 14 15 16 it 17 18 s 19 20 E 21 22 p 23	cope. BY MR. GOLOMB: Q Is what? A It says "talc." Q And from the same document, page 2 of 3, t specifically refers to talc, correct? MR. LOCKE: Objection. Beyond the cope. THE WITNESS: Yes. BY MR. GOLOMB: Q And can you just read that for the jury, olease.	12 13 14 15 16 17 18 19 20 21	the they concluded that talc was a Class 2B carcinogen, correct?  MR. LOCKE: Objection.  THE WITNESS: Based on limited evidence. BY MR. GOLOMB:  Q And in fact, this Ovarian Cancer Prevention PDQ that we're now referring to refers to the IARC report, correct?  MR. LOCKE: Objection.  THE WITNESS: Yes. BY MR. GOLOMB: Q And do you see at the bottom third of

79 (Pages 688 to 691)

	Page 692		Page 694
1	BY MR. GOLOMB:	1	BY MR. GOLOMB:
2	Q Can you just read that for us, please.	2	Q Now, just to refresh your recollection
3	A It says, quote: "Based on solid	3	before you and I'll give you whatever time you
4	evidence, perineal application of talc is	4	need when we were talking before about the PDQ,
5	associated with a small increased risk of ovarian	5	I also referred to the snapshot. Do you recall
6	cancer. The International Agency for Research on	6	that?
7	Cancer has concluded that perineal talc is a	7	A Yes.
8	possible carcinogen."	8	Q And so this is a Snapshot of Ovarian
9	Q And then it talks about the magnitude of	9	Cancer from the NCI website. Do you understand
10	the effects, correct?	10	that?
11	A It does.	11	MR. LOCKE: Objection. Beyond the
12		12	scope, lack of foundation, form.
13	Q And it says an odds ratio of 1.24, correct?	13	THE WITNESS: Yes.
14		14	BY MR. GOLOMB:
15	MR. LOCKE: Objection.	15	
	THE WITNESS: That's what it says. BY MR. GOLOMB:	16	Q And that's dated August 8th, 2016,
16		17	correct?
17	Q Meaning that there is nearly a 25		MR. LOCKE: Same objections.
18	percent increased risk of harm, correct?	18	THE WITNESS: Yes.
19	MR. LOCKE: Objection.	19	BY MR. GOLOMB:
20	THE WITNESS: Well, there's a confidence	20	Q Have you have you seen this document
21	interval with that, but that's a that's what	21	before?
22	the odds ratio is.	22	A Again, I well, I think I've seen
23	BY MR. GOLOMB:	23	something from NCI once upon a time. It would
24	Q Right. And do you have enough	24	be I don't know what the date would be, so my
25	experience in epidemiology to understand that that	25	answer's going to be no.
	Page 693		Page 695
1	Page 693 is statistically significant?	1	Page 695 Q Okay. And
1 2		1 2	
	is statistically significant?  MR. LOCKE: Objection. Beyond the scope.		Q Okay. And
2	is statistically significant?  MR. LOCKE: Objection. Beyond the	2	Q Okay. And MR. LOCKE: I also want to note this is
2 3	is statistically significant?  MR. LOCKE: Objection. Beyond the scope.	2 3	Q Okay. And MR. LOCKE: I also want to note this is just one of six pages.
2 3 4	is statistically significant?  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I think it depends	2 3 4	Q Okay. And MR. LOCKE: I also want to note this is just one of six pages. MR. GOLOMB: Right. And this is the
2 3 4 5	is statistically significant?  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I think it depends  MR. LOCKE: Calls for expert testimony.	2 3 4 5	Q Okay. And MR. LOCKE: I also want to note this is just one of six pages. MR. GOLOMB: Right. And this is the page that refers to talc.
2 3 4 5 6	is statistically significant?  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I think it depends  MR. LOCKE: Calls for expert testimony.  THE WITNESS: Yeah, it depends on what	2 3 4 5 6	Q Okay. And MR. LOCKE: I also want to note this is just one of six pages. MR. GOLOMB: Right. And this is the page that refers to talc. BY MR. GOLOMB: Q Do you see in the lower half portion of that page, the Snapshot of Ovarian Cancer, under
2 3 4 5 6 7	is statistically significant?  MR. LOCKE: Objection. Beyond the scope.  THE WITNESS: I think it depends  MR. LOCKE: Calls for expert testimony.  THE WITNESS: Yeah, it depends on what study you're looking at. And I I'm surprised	2 3 4 5 6 7	Q Okay. And MR. LOCKE: I also want to note this is just one of six pages. MR. GOLOMB: Right. And this is the page that refers to talc. BY MR. GOLOMB: Q Do you see in the lower half portion of
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80 (Pages 692 to 695)

	Page 696		Page 698
1	of talc.	1	heard that, that any of those other risk factors
2	MR. GOLOMB: Okay. Can we go to the	2	are in dispute?
3	next document, please.	3	MR. LOCKE: Objection. Beyond the
4	BY MR. GOLOMB:	4	scope.
5	Q And just for the record, this is a	5	THE WITNESS: No. I I've never heard
6	document which previously was marked for	6	of tall height before, but that's just me.
7	identification as P-645.	7	BY MR. GOLOMB:
8	(Exhibit No. 78 was marked for	8	Q But at least of again, this is dated
9	identification.)	9	December 13th, 2017, on the Snapshot of Ovarian
10	BY MR. GOLOMB:	10	Cancer, the NCI identifies the use of talc as a
11	Q So this is another shot of the	11	risk factor, correct?
12	website of the NCI website, A Snapshot of	12	MR. LOCKE: Same objection.
13	Ovarian Cancer. Correct?	13	MR. DUFFY: Beyond the scope.
14	A Yes.	14	MS. FRAZIER: Same objection.
15	Q And if you look at the bottom of the	15	THE WITNESS: That's what it says.
16	page, it's dated October 14th, 2016, correct?	16	BY MR. GOLOMB:
17	A Yes.	17	Q And so if I understand your your
18	Q And if you look at the third full	18	testimony correctly, you have never seen any of
19	paragraph, again it identifies the use of talc as	19	these PDQs before, correct?
20	a risk factor, correct?	20	A I think at some point I probably saw a
21	MR. LOCKE: Objection.	21	PDQ. I can't remember when or or what. Again,
22	THE WITNESS: Yes.	22	we we didn't have any contact at all with NCI
23	MR. LOCKE: Lack of foundation, scope,	23	or any connection, but I know I heard about it at
24	form, and it's one page of six.	24	some point.
25	MS. FRAZIER: Join.	25	Q Okay. And and did you did you
	Page 697		Page 699
1	Page 697 BY MR. GOLOMB:	1	Page 699 learn at some point that after December 13th,
1 2		1 2	
	BY MR. GOLOMB:		learn at some point that after December 13th,
2	BY MR. GOLOMB:  Q Okay. Let's go to the next document.	2	learn at some point that after December 13th, 2017, that the NCI took the use of talc off of its
2	BY MR. GOLOMB:  Q Okay. Let's go to the next document.  MR. GOLOMB: What's the number of this?	2 3	learn at some point that after December 13th, 2017, that the NCI took the use of talc off of its website?
2 3 4	BY MR. GOLOMB:  Q Okay. Let's go to the next document.  MR. GOLOMB: What's the number of this?  MR. LOCKE: 79.	2 3 4	learn at some point that after December 13th, 2017, that the NCI took the use of talc off of its website?  A I couldn't have told you what the date
2 3 4 5	BY MR. GOLOMB:  Q Okay. Let's go to the next document.  MR. GOLOMB: What's the number of this?  MR. LOCKE: 79.  BY MR. GOLOMB:	2 3 4 5	learn at some point that after December 13th, 2017, that the NCI took the use of talc off of its website?  A I couldn't have told you what the date was, but at some point I did learn that it was not
2 3 4 5 6	BY MR. GOLOMB:  Q Okay. Let's go to the next document.  MR. GOLOMB: What's the number of this?  MR. LOCKE: 79.  BY MR. GOLOMB:  Q Okay. This is Exhibit 79.	2 3 4 5 6	learn at some point that after December 13th, 2017, that the NCI took the use of talc off of its website?  A I couldn't have told you what the date was, but at some point I did learn that it was not listed there.
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Page 702 Page 700 1 Q Okay. So as you sit here today, you 1 reports, and I know there was some question as to 2 recall that the NCI removed it from its website. 2 what was actually found, but there were reports, I 3 You don't remember how you -- how you learned 3 believe in the newspaper, from findings out of --4 that, and you don't know how that got off the 4 I think it was Mount Sinai Hospital or -- anyway, 5 5 website. Is that your testimony? of the finding of asbestos in talc. 6 A Correct. 6 Q And that was -- was that the finding of 7 Q Okay. Let's talk about the Talc 7 asbestos in talc, that talc specifically being 8 8 Interested Party Task Force. And I -- we've found in the ovarian tissue? talked a lot about this in the last deposition, 9 9 A No. I thought it was just talc being 10 10 found in -- excuse me -- asbestos being found in and so I'm going to try not to repeat myself. 11 But to be clear, there are various 11 talcum products. 12 records, some of which -- most of which refer to 12 Q Just generally? 13 the Talc Interested Party Task Force, some of 13 A Yes. 14 which refer to the Interested Party Task Force. 14 Q All right. And so you don't have a 15 They're one and the same; is that correct? recollection one way or the other as to what the 15 16 16 Henderson study concluded? A That's correct. A My recollection of the Henderson study 17 Q Do you know when the task force was 17 18 18 is that they were reporting the finding of talc in created? 19 ovaries, but I believe they also found them in 19 A I believe it was created in 19 -- maybe controlled women that hadn't been exposed to talc. 20 '71, or early '70s. 20 21 Q And why was it created? 21 22 22 A In response to the finding of asbestos Q Okay. And as you sit here today, do you or the reporting of asbestos in talc. know one way or the other as to whether or not 2.3 23 24 Q Okay. Well, was it the reporting of 24 the -- the Talc Interested Party Task Force was 25 asbestos or was it the reporting of talc in the 25 created before or after the Henderson study? Page 701 Page 703 1 1 MR. LOCKE: Objection. Asked and ovarian tissue? 2 A I thought it was the reporting of 2 answered. 3 asbestos. 3 THE WITNESS: As far as I'm aware, it 4 Q All right. You -- you were asked 4 was created in response to the asbestos issue. 5 5 earlier by Mr. Tisi about the association between BY MR. GOLOMB: 6 talc and ovarian cancer, and I think -- correct me 6 Q Okay. Well, that -- but that wasn't my 7 if I'm wrong, I think you said that you -- that 7 question. My question was, do you know one way or 8 "you," meaning PCPC, CFTA -- first learned about 8 the other as you sit here today -- because you 9 that potential association in 1982 after the 9 don't -- you don't know the chronology of the --10 Cramer study. Was that your testimony? 10 the asbestos finding and the Henderson study, 11 A I believe that's correct, yes. 11 correct? 12 Q Are you familiar with the Henderson 12 MR. LOCKE: Objection. THE WITNESS: Yeah, I don't know the 13 study? 13 14 A I do know what you are talking about, 14 year of the Henderson study. BY MR. GOLOMB: 15 15 yes. 16 Q And that was in the early '70s, correct? 16 Q Right. But my question to you is a very A That sounds right. 17 specific one, and that is, do you have a 17 18 Q All right. Was the Talc Interested 18 recollection one way or the other as to whether or 19 Party Task Force formed in response to the 19 not the Talc Interested Party Task Force was 20 Henderson study? 20 created in response to the Henderson study? 21 21 MR. LOCKE: Objection. Asked and A I believe it was formed in response to 22 the asbestos finding. 22 answered. 23 Q All right. And when you say "asbestos 23 THE WITNESS: What's the question? Was finding," what are you referring to? 24 24 it in response --25 A Well, I'm referring to the newspaper MR. GOLOMB: Can you read back the

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Page 704 Page 706 1 could where we think we might have members who are 1 question, please. 2 THE WITNESS: I believe no. 2 interested, should know about this, and then see 3 3 if they're interested in again, you know, taking BY MR. GOLOMB: 4 4 on further activities related to a particular Q Okay. 5 5 A I believe it was created in response to topic. 6 6 Q And when you say "further activities," the asbestos issue. 7 7 Q And when you say "in response," what was what kind of activities? 8 8 the purpose of it? A It totally depends on what the task 9 9 A To address -- when there was the force is. Like I say, in the case of the talc-10 asbestos issues, then it was putting together a 10 finding, it was to look further into that to see if it was real, and then ultimately to come up 11 11 specification -- or, rather, there was a talc 12 specification, but adding in asbestos -- asbestos 12 with a specification so that -- to confirm that 13 there was no asbestos in talc. 13 to that specification and working on methods to --14 14 Q And -- and how is -- how is a task force for protection. 15 Q And one of the, as you say, further 15 like that created? 16 A So in general, if you -- I mean, if 16 activities is the hiring of scientists, correct? 17 there's a finding, then basically we inform our 17 A Well, it could be. 18 members, and we look for interest in pursuing some 18 Q Right. And it was in the case of the 19 19 talc -- the talc task force, correct? activities related to a -- a particular issue. 20 And in those -- those people again would, on their 20 A I'm not sure what you mean by "hiring of 21 own then, that would be the group that would 21 scientists." 22 22 decide where do we go from here, what do we do. Q Well, at some point in time in the -- in 23 response to the Citizens Petition, in response to 23 Q Okay. So it comes from you, meaning the 24 PCPC, rather than the members coming to you and 24 the NTP preliminary findings, the members of the 25 saying, you know, I just read something, this may 25 PCPC at that time, the CFTA, who were also a Page 707 Page 705 1 member of the Talc Interested Party Task Force, 1 be something that we need to create a task force 2 for? 2 funded the hiring of scientists and experts to 3 A Oh, no, it depends. It can go either 3 defend them in front of the NTP and to respond to 4 way. It can be us finding something. It's 4 the -- to the Citizens Petition, correct? 5 5 basically -- what our role would be then to A That can be one of the activities that 6 disseminate that information to see if there is 6 we undertake, yes. 7 7 interest in forming a task force and -- and taking O But it's --8 8 on further activities. A It can be doing a study, it could be 9 9 hiring a scientist or hiring a consultant, I Q Okay. And in the case of the Talc 10 Interested Party Task Force, was that something 10 guess, to look at an issue. 11 where the -- the CFTA went through its members or 11 Q Okay. 12 one of its members came to the CFTA? 12 A It could be any number of things. 13 A I think I'd have to say I don't know. 13 Q Okay. And -- and I think we can agree 14 Q Did you go back and -- there's minutes 14 that the -- the funding of the -- these task 15 of these -- of these meetings, right? 15 force, and the talc task force in particular, is 16 A Yes. 16 not your bailiwick, so to speak, correct? A Yes. I mean -- I mean, I could speak 17 Q So let me ask you generally, when the 17 idea is created to -- to create a task force, how 18 generally to funding of task forces. I mean, 18 19 obviously depending on how much funding is 19 is it then implemented? 20 20 available and where people's level of interest in A We would go out to -- in general, and 21 21 this is -- since this was years before, it's going helps define what your future activities are. 22 to be a little bit of a different setup that I'm 22 Q No, but I -- I understand that. But my 23 not going to be aware of, but we would go out to 23 question is, if I were to ask you specific 24 committees where we think there might be interest, 24 questions about the funding of the talc task 25 we would try to spread the word as widely as we force, that is not your bailiwick.

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Page 708 Page 710 1 A That was Mark Pollack. 1 Q Well, as you -- as you said in your --2 Q Right. And so were you -- were you ever 2 your testimony just earlier today, the -- you see 3 3 shown the -- the chart that Mr. Pollack created this -- whether it was the Henderson study or what 4 4 you said was that asbestos was found in the talc, for us where -- for this litigation which 5 5 identifies how much was deposited into the account that the -- the CFTA then went to its members to 6 of the Talc Interested Party Task Force over the 6 determine the level of interest for a task force, 7 7 correct? vears? 8 8 A I think I've seen that, yes. A I said that --9 Q Okay. And so that was somewhere close 9 MR. LOCKE: Objection. 10 10 to half a million dollars, correct? THE WITNESS: Yeah, I said that's how 11 A I mean that -- that sounds about right. 11 generally it works. I mean, I'm not sure exactly 12 Q And about 67 percent of that was funded 12 how that happened. But, yes, we -- we would want 13 specifically by J&J and Imerys and the 13 to inform our members, because that's one of the 14 predecessors of Imerys, correct? 14 things we do, inform them what issues might be 15 15 A That's what I heard this morning, yes, related to them, and then we would generally 16 and that sounds right, consistent. 16 spread the word, is there interest, is there 17 Q And I think you said something -- that 17 something that, you know, we should form a task 18 there were something like 18 or 20 different 18 force for. So I assume that's the way it went 19 members of the task force. 19 there basically. 20 A I'm not sure there's -- I don't think 20 BY MR. GOLOMB: 21 there was more than that, but there was probably 21 Q And people you think may be interested 22 22 are then in some form or fashion contacted? close to that. Fifteen. 23 Q All right. And so the other 16 or so 23 A Well, we would contact -- now -- now 24 members of the task force put up a third of the 24 certainly -- again, things were a little different 25 funding, and Imerys and J&J put up the balance? 25 back then, but now we would contact through our Page 709 Page 711 1 A That -- that could be. 1 committees. We have a Safety and Regulatory 2 2 Q Okay. And once the task force is -- is Toxicology Committee. It's a very large committee 3 created, what happens next? 3 with a very large mailing list, so that gets to a 4 4 A Well, I mean, then they would get lot of people. We have a Scientific Advisory 5 5 together and talk about it, and what activities do Executive Committee now, it now has a different 6 we undertake, what do we understand about this, 6 name, but -- and again, there would be more people 7 7 what questions, is there -- you know, what we would contact. So we would make sure we spread 8 8 follow-up is needed to understand what the issue the word because we're just trying to make sure 9 9 everybody knows what's going on and see if they is, and where do we go from here. And then if it 10 comes to things that cost money, then it was like 10 have interest. 11 11 going out and getting proposals or -- and seeing Q And then at some point, whether it's 12 what people want to do. 12 1971 or the way you do it now, once you assess 13 those responses, you have a meeting of some sort, 13 Q Okay. And what happened in this case, 14 in the case of the Talc Interested Party Task 14 whether it's in person or telephone. Correct? 15 15 Force? When -- when was it first discussed A Generally, right, we -- then once we had 16 16 amongst its members? identified interested people, then we would want 17 17 A Are you talking about 1971 when it was to get that group together. 18 Q Okay. And then the -- those interested 18 first formed? 19 parties are identified, some employees of the CFTA 19 Q Well, if that's when it was. 20 20 at the time are then kind of the ones in charge of A I mean, then there were discussions 21 21 ongoing about asbestos, and we need methodologies having that liaison with the members on that 22 22 particular task force, correct? so we can detect if there's asbestos in talc, 23 and -- and there was a great deal of activity 23 MR. LOCKE: Objection.

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THE WITNESS: Yes. Somebody -- somebody

would -- from the association would be involved.

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well.

related to that, which included FDA activities as

Page 714 Page 712 Q Okay. I'm showing you Exhibit 80, which 1 BY MR. GOLOMB: 1 2 Q Okay. And when this -- when this task 2 is the cover page of those minutes. 3 3 Take -- take whatever time you need just force was first created, who was that person from 4 4 the CFTA? to read that. 5 5 A I believe it was -- at the time I think A (Peruses document.) Okay. б 6 Q Okay. Now, when you have a -- a task we only had one science person, so it was Norm 7 7 force like this, is somebody appointed as a -- as 8 8 a chairman of sorts of the committee? Q I'm sorry? 9 A Norm Estrin, I believe. 9 A It depends. Sometimes yes, sometimes 10 O And then there was -- there was in some 10 no. 11 form or fashion a meeting held of the prospective 11 Q What does it depend on? A The nature of the committee, the people 12 interested parties? 12 13 A Yes. I mean, I looked at a lot -- a lot 13 who are on it. Q Okay. And do you recall in -- in this 14 of minutes and there were a lot of meetings held. 14 15 Q Okay. Did you see minutes from the -particular case whether or not a chairman was 15 16 from back -- dating back to 1971? 16 nominated and then agreed to? 17 A I don't know about '71. 17 A You know, I recall in the case of going 18 O Well, when was the first --18 back to the '70s when the specifications was going A I saw them back to the '70s. 19 on, I think there was a chair for that effort 19 20 Q Okay. Because I'll represent to you 20 around developing methodology. I think there was 21 that the first meeting minutes that we have which 21 also a chair on kind of the more overarching talc, 22 refers to the, quote, ad hoc talc task force is 22 not the -- I know I'm not answering your question. I'm just trying to think here. 2.3 1982. 23 24 Were there minutes before that? 24 Do I recall if there was one here? I 25 A I know I saw documents relating to 25 guess I'd have to say I don't recall. Page 713 Page 715 working on specifications. I thought they were 1 1 Q Okay. Is it -- is it consistent with minutes. Maybe I'm wrong, but I know I saw 2 2 your recollection that there was maybe some 3 documents relating to that. 3 activity surrounding the asbestos issue in 1971, 4 and then no longer activity until 1982, when the 4 Q Okay. And the date of the first task 5 5 force minutes, which I'll show you in a minute, Cramer study came out? 6 are dated November 11th, 1982. Do you recall 6 MR. LOCKE: Objection. 7 7 seeing minutes from November 11th, 1982? THE WITNESS: No, there was activity in 8 the '70s relating to the asbestos and development 8 A I wouldn't recall a precise date. I 9 9 of -- of methodology that went well into the '70s. know that there were minutes going into the '80s, 10 and that would have been after the Cramer study. 10 BY MR. GOLOMB: Q Okay. And would there have been various 11 11 12 12 meetings in the '70s, whether they were by Q Right. And that's -- that was my next 13 question. That is a date which coincides shortly 13 telephone or in person? 14 after the Cramer study. 14 A I believe that's correct, yes. 15 A Okay. 15 Q And are -- whether the meeting is held by telephone or in person, are there minutes of 16 Q So is that consistent with your 16 17 recollection that there was minutes of the ad hoc 17 those meetings? A Again, I'm -- I mean, I've seen things 18 talc task force shortly after the Cramer study was 18 on developments of them. Were they minutes or 19 published? 19 20 20 were they otherwise memos? Off the top, I don't A I know that there was definitely -- that 21 the task force got together after the Cramer study 21 know. I thought they were minutes. I could be 22 was published, yes. 22 wrong. 23 (Exhibit No. 80 was marked for 23 Q Okay. And was a -- was a chairman of 24 24 identification.) this particular committee appointed before 25 BY MR. GOLOMB: 25 November 11th, 1982?

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Page 718 Page 716 1 A Well, if there's a chairman appointed on 1 A Yes. 2 the asbestos -- on the earlier work, that doesn't 2 Q All right. And you -- you told us 3 3 mean that would be the same chairman in 1982. earlier that you read the various minutes of this 4 4 committee to prepare for your deposition, correct? Q Okay. And do you know who Dr. Bruce 5 A I read some minutes from this committee, 5 Semple is? 6 б yes, or this task force. A I think I've heard the name. He's at --7 I want to say P&G. 7 Q All right. And generally -- I'm sorry? 8 8 A Task force, I guess we call it. Q I'm sorry? 9 A I want to say Procter & Gamble, but I 9 Q Right. And generally, what was the goal 10 could be wrong. 10 of the task force back in November of 1982? 11 Q Okay. Well --11 A Well, I think just from the minutes, it 12 A Only because I've seen the name. I 12 was -- the concern was the ovarian cancer issue, 13 don't believe I've met the person because that 13 just given that the study had come out, the Cramer study. And I know in minutes I've seen, and this 14 would have been too long ago. 14 Q If I told you there's a document that refers to them, a thought of doing a study to look 15 15 16 says: "On November 11, 1982, nominations were 16 at translocation. So I think that was certainly 17 taken from the committee to elect a chairman. 17 one of the big discussion points. 18 After discussion, the task force agreed to elect a 18 Q Okay. And when you say "look at 19 19 translocation," what do you mean? chairman and a vice-chairman. Dr. Bruce Semple 20 from Johnson & Johnson was unanimously elected 20 A Trans -- talc can translocate from the 21 chairman. Dr. Edward Jackson from Knoxville was 21 perineum to the ovary. 22 22 Q Okay. And what was -- what was done by unanimously elected vice-chairman." 23 Would that refresh your recollection? 23 the CFTA back in 1982 in conjunction with the task 24 MR. LOCKE: Objection. Let the record 24 force to address that issue? 25 reflect that counsel is reading from pages that 25 A So there were -- I think it was actually Page 717 Page 719 1 have not been shown to the witness, probably of 1 two studies, although I think one was kind of a 2 the very same minutes that we're seeing the cover 2 beginner study leading to a bigger study with 3 3 monkeys using radio tracers, I think three page of. 4 4 BY MR. GOLOMB: different radio tracers, that was implanted in the 5 5 Q I will refer you to page 2, subsection 4 monkey vaginas, and it was -- then it was assessed 6 under Administrative Chairman, and take a look at 6 whether they could -- the talc would translocate 7 7 that and tell me if I read that accurately. to the ovary. 8 8 A Yes, you read it accurately. Q Okay. And then what was done next by Q Thank you. 9 9 the task force or any of its members? 10 Who is H. Joseph Sekerke, Ph.D.? 10 A I -- I don't know what you mean. 11 A He is a -- was a CTFA employee 11 Q Well, do you know one way or the other 12 12 as to whether or not any of the members were then scientist. 13 Q Okay. So would he have been that person 13 sent out to go talk to Dr. Cramer about his -- his 14 that liaison that we discussed earlier of this 14 paper? 15 particular committee in 1982? 15 A I'm not sure. If you can show me 16 A I think that would be likely. 16 documents that can refresh my memory. Q Okay. And that's who these minutes were Q Well, I'm just asking you, based on your 17 17 signed by -- he just writes "Joe," Joe Sekerke. understanding as you sit here today whether or not 18 18 19 A It makes sense. I mean, it -- again, Dr. Semple went to go talk to Dr. Cramer? 19 20 the science staff was very small at that point, so 20 A I don't remember. I mean, I may well 21 21 that was up from one to two at least. So that have looked at those documents. I just don't 22 22 makes sense. remember. 23 Q Okay. And you mentioned that in -- in 23 O Okay. And what else in the 1980s did 24 1982, we agree that Dr. Semple was the chairman of 24 the task force do? 25 this committee, correct? 25 A 1980s -- sorry. I just need to think.

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Page 720 Page 722 1 I -- I don't remember. I mean, I know 1 his paper was circulated to the members of the 2 that was the big study that was done. 2 task force before it was published? 3 3 Q I'm sorry. A I believe it was. 4 A That was the big study that was done. 4 Q Okay. And is it -- is it your -- your 5 5 Again, if you show me documents to refresh my experience that that is a -- is an ethical 6 memory, that would be --6 approach to the publication of a paper, to 7 Q All right. And is it fair to say that 7 circulate it to people who have a financial 8 whether it's the -- the Talc Interested Party Task 8 interest in the outcome of the paper before it's 9 9 Force or any other task force, that they don't published in a scientific journal? 10 10 necessarily meet on a regular basis, but they meet MR. LOCKE: Objection to form and beyond 11 kind of depending on the activity of the -- that 11 the scope. 12 12 would be interesting -- interested to the task THE WITNESS: What -- what we -- the 13 force? 13 comments that we're looking for are typos, 14 14 clarity. We can't question the conclusion of the A That is correct, particularly with the 15 authors, and when we're hiring ethical people, 15 task force. We have some standing committees that 16 16 they're not going to let us do that. meet regularly, but task force, almost by 17 17 definition, are responding to specific issues. BY MR. GOLOMB: 18 Q Okay. So do you know one way or on the 18 Q Okay. So then -- so you have -- you --19 19 other as to whether or not there was a meeting of the task force meets. They agree on an approach, 20 20 the task force between November 11th, 1982, and in this case the approach is to -- is to contact 21 September 16th of 1993, which I'll represent to 21 and retain Dr. Gross, give Dr. Gross kind of his 22 22 you is the -- I'm sorry -- February 2nd, 1993, marching orders of what he is going to do. He 23 23 which is -- I'll represent to you is the -- the goes out and does it. The -- the money is then 24 next minutes that we have? 24 funded by the task force comes from your 25 MR. LOCKE: Objection. 25 organization. It's then circulated, and you meet Page 721 Page 723 1 THE WITNESS: I -- I don't know. 1 to discuss the -- the -- what potential 2 BY MR. GOLOMB: 2 typographical errors. Is that your testimony? 3 Q All right. Do you know, based on your 3 MR. LOCKE: Objection to form. 4 recollection of your preparation for this 4 THE WITNESS: No, that wasn't my 5 5 deposition, as to whether or not there was testimony. I guess it would just be helpful if I 6 something that was going on between 1982 and 1992 6 could see the documents. 7 that would have interested the task force? 7 I mean, we -- when we -- when we hire a 8 A I mean, I think -- I think there were 8 consultant, yes, we do look at -- and there are 9 9 papers that were looked at, but I couldn't be more areas that we have -- industry has knowledge that 10 specific than that at this point. Again --10 a consultant may not. We're hiring -- for 11 Q Papers looked at by whom? 11 example, if we're hiring somebody who is an expert 12 A I think there may have been ovarian 12 epidemiologist, we can't question his epi---13 cancer papers that were looked at. But again, if 13 their epidemiology findings, but we may have more 14 you can show me something to -- to help my memory, 14 knowledge about how talc is used by a consumer, 15 that would be great, but -- I know there were big 15 how -- you know, questions about analysis of talc, 16 things going on in '93, but --16 purity of talc, mining, mineralogy. 17 Q Okay. And then as -- as you were 17 So we're reviewing it as -- with some questioned earlier today by Mr. Tisi, Dr. Gross 18 18 expertise, and as well as saying, you know, if we 19 was then hired in 1993, correct? 19 get a document back and we think there could be 20 A Was that '93? Yes. 20 more clarity, I mean, I think it's okay to say to 21 21 Q All right. And that's when he -- he an author, Could you clarify a little more what 22 published his meta-analysis, correct? 22 you mean here. 23 23 BY MR. GOLOMB: 24 24 Q Well, does the -- does the document --Q And do you know one way or the other as 25 to whether or not Dr. Gross's paper or draft of 25 once the -- once the draft from the outside expert

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Page 724 Page 726 1 is -- is written, does that paper then go to the 1 A I -- I don't know. 2 CTFA or does it go to one of the members? 2 MR. LOCKE: Objection. 3 A Typically -- typically it would go -- if 3 BY MR. GOLOMB: 4 CTFA is the one, or PCPC, is arranging that, then 4 Q If you just read the second paragraph, 5 you'll see: "It has been proposed that we arrange 5 it would come back to us, and then we would 6 6 for Dr. Gross to publish his analysis." Do you distribute it to the task force. 7 Q Okay. Have you ever seen a situation 7 see that? 8 where an expert was hired and the draft went to an 8 A Yes. 9 industry member before it went to -- to the CTFA 9 Q And then the next sentence says: 10 10 and was circulated to its members? "Johnson & Johnson will arrange for preparation of a first draft, which will then be reviewed by the 11 A Only --11 12 task force." Correct? MR. LOCKE: Objection. 12 THE WITNESS: Only the one we talked 13 13 A Yes. 14 about this morning. 14 Q Okay. Is that the first time you've 15 BY MR. GOLOMB: ever seen anything like that where a member -- an 15 16 O Which one was that? 16 industry member gets the first draft of -- and 17 A The Huncharek/Muscat review. 17 then they circulate it? 18 Q Okay. Let me show you the next 18 MR. LOCKE: Objection. 19 MS. FRAZIER: Object to form. 19 document. THE WITNESS: Well, as I say, the one 20 MR. GOLOMB: This is Exhibit 81. 20 21 (Exhibit No. 81 was marked for 21 this morning would be the other one, but "will 22 22 identification.) arrange for the preparation," so I guess they're the interface with the consultant. And then it 23 BY MR. GOLOMB: 23 24 Q And for the record, this is a memorandum 24 will go to the task force. So I'm not sure if J&J 25 dated September 22nd, 1993, from Stephen Gettings, 25 is reviewing the draft. They're arranging for the Page 725 Page 727 1 Ph.D., to the Talc Interested Party Task Force. 1 draft to be prepared is how I'm reading this. BY MR. GOLOMB: 2 First of all, let me just ask you for 2 3 the record, Dr. Gettings was the director of 3 Q Okay. So that -- that's how you read toxicology at that time, correct? "Johnson & Johnson will arrange for a preparation 4 4 5 5 of a first draft"? A Yes. 6 Q And was there overlap between 6 A Probably, yeah. I don't -- I don't know 7 Dr. Gettings being the director of toxicology and 7 for sure. the time that you came to the CTFA? 8 8 Q So you don't -- as you sit here, you 9 A No. 9 don't know one way or the other as to whether 10 Q When did Dr. Gettings leave? 10 Johnson & Johnson received that first draft? A I -- well, I started in October of '97, 11 11 A No. 12 and he left soon before then. He had actually 12 Q And if so, you don't know what happened moved over to the legal department and was there to that first draft once it was reviewed by 13 13 14 very briefly, and then he moved on to -- he went 14 somebody at Johnson & Johnson and then circulated 15 to a member company. 15 amongst the task force members, correct? 16 Q And who replaced Dr. Gettings? 16 MS. FRAZIER: Object to form. A I did. MR. LOCKE: Objection. 17 17 Q All right. And so have you seen this 18 THE WITNESS: Yeah, I don't know if J&J 18 19 reviewed the draft, it went straight to the task 19 document before? A I don't know. I want to say I don't 20 20 21 21 think so. BY MR. GOLOMB: 22 Q Okay. So this is a CF -- CFTA document 22 Q Okay. And then it says if you -- quote in big -- in capital letters, bold: "If you DO dated September 22nd, 1993, and you did not see 23 23 NOT AGREE with this proposed course of action, 24 this in your preparation of now Day 3 of a 24 25 deposition? 25 please contact me by close of business, COB,

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Page 730 Page 728 1 1 Monday, September 27th, 1993." Correct? gathers in some form or fashion, or maybe there's 2 A That's what it says, yes. 2 some leadership to the group, like Dr. Semple and 3 3 some others, that say, Okay, this is reasonable, Q And are you aware one way or the other 4 as to whether or not anybody objected to that? 4 go ahead, and then the -- the CTFA can you tell us 5 5 A No, I would not be aware. a check. 6 6 Q And is it generally the -- the role at A We do a contract, and we would be the 7 the CFTA at the time that they review any document 7 ones who would pay, yes. 8 8 before it's published? Q Okay. Have you ever seen a situation 9 9 MR. LOCKE: Objection. where the -- the industry member pays for it 10 10 THE WITNESS: I would say we -- we themselves? 11 generally review documents before they're 11 A Not in my experience, that's not how 12 published, yes. 12 it's worked. 13 BY MR. GOLOMB: 13 Q Okay. And why do you do it that way? 14 14 Why do you have -- why is the money deposited into Q Okay. And you told us one of the 15 reasons why you do that is to -- for grammatical 15 the CTFA, and then a check written from the CTFA 16 errors. Why else would you -- why else would the 16 to the expert, rather than the industry member pay 17 CFTA review publications of outside experts before 17 for it themselves? 18 they're published? 18 A Because it's multiple industry members. 19 19 A I guess, again, I would just say that So we're -- we're putting the industry resources 20 together, so we're the site where the money is there may be some expertise, some -- you know, 20 21 again, more knowledge of -- if somebody is writing 21 collected, and then we write one check to the 22 on talc, the industry knows best how it's used. 22 consultant. 23 23 If there is any question of how it's sourced, that Q Okay. Let me show you the next 24 kind of thing, whether it came up in this 24 document. 25 document, I don't know, but there are certain 25 This is 82. Page 729 Page 731 1 areas of expertise. Yeah, we're hiring them for 1 (Exhibit No. 82 was marked for 2 their epidemiology expertise. 2 identification.) 3 Q And do you -- do you know who it is that 3 BY MR. GOLOMB: 4 paid for Dr. Gross's report? Q Now, this is a letter from Dr. Alfred 4 5 5 A I believe we did. Wehner, correct? 6 Q When you say "we," you mean the PCPC? 6 A Yes. 7 A I'm sorry. PCPC, yes. 7 Q And it says it's cc'd to M. Chudkowski, 8 Q At the time CTFA? 8 correct? A Yes. 9 A Yes. 9 10 10 O Who is that? O And that would be out of money that is 11 deposited into the task force account? A Michael Chudkowski, he's a J&J person. 11 12 A Yes. That would be typical. 12 Q And is there a reason why Mr. Chudkowski 13 Q The PCPC or its predecessor CTFA was the sole member of the task force that was 13 14 wouldn't go out of pocket to pay for something 14 copied on a letter from Dr. Wehner to Dr. Gettings 15 like this, right? They would ask its members 15 in November of 1993? 16 first? 16 A I think I need to read it first. Q Okay. 17 A The activities of the interested 17 18 A (Peruses document.) parties, that's what they are -- that's what 18 19 "interested party" refers to, people who are 19 I don't know. I don't know if \$1400 was 20 willing to expend money, because you have to do 20 the whole amount, and this to me looks like this 21 that to get certain things done. 21 is not the way we normally do things. Normally, 22 Q Okay. And that so the -- the task force 22 the -- as I say, we pay them for an interested 23 members agree on a course of action, in this case 23 party. So I don't know why in this case J&J 24 24 the course of action was to hire Dr. Gross. was -- as asked being to pay. 25 Dr. Gross makes a proposal. The task force then 25 Q Okay. Let's be clear about this. Well,

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Page 732 Page 734 1 first of all, based on the letter, J&J was not 1 the Hankinson study is. 2 asked to pay, correct? J&J volunteered to pay. 2 A I know that Dr. Hankinson was an author 3 on a couple of different studies. She was -- she A Right. 3 4 MR. LOCKE: Objection. Form. 4 was one of the coauthors on the Gertig study, but 5 BY MR. GOLOMB: 5 she was also a coauthor on the Houghton study. 6 Q Right. So it says: "While you" -- it 6 Q Okay. And which study -- if there was a 7 says: "I am enclosing" -- meaning Dr. Wehner, "I 7 minutes draft -- draft of the minutes from January 8 am enclosing Dr. Gross's invoice in the amount of 8 of 1994, do you know which Hankinson study it 9 \$1400 for his professional services and expenses. 9 would be referring to? 10 A I don't. I'm trying to think what year While you mentioned, and Mike Chudkowski 10 11 confirmed, that J&J would pay the costs for the 11 the Gertig study, and I'm -- I'm blanking on that. manuscript preparation, I believe it to be (Exhibit No. 83 was marked for 12 12 13 appropriate for BEC to submit the invoice to CTFA 13 identification.) because CTFA requested the job." Correct? 14 BY MR. GOLOMB: 14 A That's what it says. Q Okay. Let me show you the Talc 15 15 16 Q Right. So they are -- although J&J has Interested Party Task Force. Now, this is -- it 16 says "Draft Minutes." I'm not sure that we have 17 volunteered to pay the full costs, at least of 17 the final minutes, but it says "Draft Minutes," 18 that particular invoice, doctor -- Dr. Wehner is 18 19 suggesting that the -- that the check be cut by dated January 11th, 1994. 19 20 the intermediary, CTFA, rather than coming from 20 Have you seen this before? 21 Johnson & Johnson itself, correct? 21 A I -- I can't recall exactly which 22 MR. LOCKE: Objection. 22 minutes I've seen. If I read it, it might seem 23 THE WITNESS: He's saying he's 23 familiar, but... 24 submitting the invoice to CTFA. So he felt from 24 Q Okay. Did -- did you read what you 25 where he sat, it should come to CTFA. 25 thought were all of the minutes of the task force Page 733 Page 735 1 1 to prepare for your deposition? BY MR. GOLOMB: 2 Q The invoice? 2 A I read a lot of them. 3 A Because then he says he expects that 3 Q Okay. we're going -- that CTFA is going to forward the A This is why I thought Bruce Semple was 4 4 5 5 from Procter & Gamble because he moved over to it. invoice to J&J. 6 Q Well, it says: "When you forward the 6 I think -- I believe I did read these. invoice to J&J, please have them pay out the check 7 7 Q Okay. And attached to that, which is 8 to Alan Gross and send it to them directly." 8 Bates-stamped J&J 15618, which is the second 9 So J&J is paying directly. 9 page -- well, it's the second page of this 10 A That's what it says, yes. 10 exhibit. It's the third page of the full 11 Q Okay. And that's why that letter was document. The second page just saying 11 12 copied to Mr. Chudkowski, right, because --12 "Adjournment" and the signature of Steve Gettings. Do you see it says "Draft" on the next 13 13 14 Q -- he is with J&J, and J&J volunteered 14 page? 15 15 A I'm sorry. Oh, yes, it says "Draft." to pay. 16 Q First of all, how were -- how were these 16 A Correct. So this is not, I would say, minutes created? Why -- why are there draft 17 the usual way that we pay. 17 Q In fact, you've never seen it done that 18 18 way before or since, correct? 19 19 A Again, this is before my time. I can 20 MR. LOCKE: Objection. 20 tell you how we do it now, but I think it was the 21 21 THE WITNESS: I think that's true. same then, is generally someone would draft 22 BY MR. GOLOMB: 22 minutes, and then it would go out to the group so 23 Q Do you know what the Hankinson study is? 23 people could look, and if they said, You know, I 24 A What year does it refer to? remember this a little differently, or really you 24 25 Q Well, I'm just asking if you know what 25 should -- we talked about this too, and it doesn't

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Page 736 Page 738 1 seem to be here. Just so members would have a 1 Q Okay. And do you know in this case how 2 chance to -- to input so that they were accurate. 2 the Hankinson study was identified? 3 3 Q Okay. And these minutes are dated A No, I don't. 4 January 11th, 1994. And if you look at page 2, 4 Q And then there was a conference -- some 5 one of the topics that was discussed was ovarian 5 sort of conversation or communication between the 6 cancer. Do you see that? 6 CTFA and the task force members about that study, 7 A Yes. 7 correct? 8 8 Q And it refers to the recent paper by A Yes. 9 Dr. Hankinson, correct? 9 Q And Mr. Chudkowski then agreed to 10 A Yes. 10 contact Dr. Gross, who had been hired and was in 11 Q And under paragraph 2, it says "M. 11 the process of drafting a -- essentially a report 12 Chudkowski." Again, Michael Chudkowski from J&J, 12 in defense of the -- the industry from the 13 correct? 13 Citizens Petition that was filed in 1993, correct? 14 A Yes. 14 A Yeah, I think that's right. He was 15 Q It says: "Agreed to contact Dr. Gross 15 doing a meta-analysis. So... 16 to discuss incorporation of the results of the 16 Q Okay. And do -- are you aware one way 17 Hankinson study in his meta-analysis manuscript." 17 or the other as to whether or not there were any 18 Do you see that? 18 other studies that were published in that A Yes. 19 19 intervening time between the time that Dr. Gross 20 Q So in this case you have a -- what 20 was hired and the time that he finalized this 21 was -- what was Mr. Chudkowski's title at J&J? 21 report? 22 A Oh, I don't know. 22 A No, I'm not. 23 O Was he -- was he an executive of some 23 Q Okay. So you don't know one way or the 2.4 sort? 24 other as to whether or not there are other 25 A I don't know. I think he was a 25 reports, other papers other than the Hankinson Page 737 Page 739 1 1 scientist. I remember him being on phone calls, study, which in fact confirm the association 2 but I'm not sure I ever knew his title. 2 between talc and ovarian cancer; is that correct? 3 Q What kind of scientist was he? 3 MR. LOCKE: Objection. 4 A I just know he participated on technical 4 THE WITNESS: There's also -- there's 5 5 reference here to another study as well. phone calls, so... 6 Q All right. So a member of the -- an 6 BY MR. GOLOMB: 7 7 industry member of the task force saw -- how was Q Okay. Do you know one way or the other 8 8 as to whether or not that study confirms the the -- first of all -- strike that. 9 9 association between talc and ovarian cancer? How was the Hankinson study distributed 10 amongst the task force members? 10 Q Okay. Are you -- are you familiar with 11 A The fact that it says this 94TA03, 11 12 that's -- that was what we used to use, a system 12 the NTP inhalation study? 13 we used to use. We used to mail them out, so I --13 A Yes. 14 that would -- in '94, I think that would probably 14 Q And what did the NTP inhalation study conclude? 15 be correct, and we would number them accordingly 15 16 sequentially. 16 A It concluded that talc -- inhaled talc 17 Q Okay. So it would be somebody -- just 17 was carcinogenic to female rats, caused lung so we're clear on this, somebody from the CTFA in cancer. There was no evidence of carcinogenicity 18 18 their role as whatever they do at the CTFA, would 19 19 in male or female mice, and I believe it was 20 see the Hankinson study, and then the Hankinson 20 equivocal evidence in male rats. 21 study would be circulated to the members of the 21 Q Okay. And anything else? 22 task force? 22 A That they concluded? 23 A It could be that. It also could be a 23 O Yeah. 24 member bringing something to our attention that we 24 Well, that was the main point, I guess. 25 would circulate. 25 When was the last time you reviewed the

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Page 742 Page 740 1 NTP inhalation study? 1 and ovarian cancer, correct? 2 A I didn't review the report. I reviewed 2 A That's about right. 3 3 Q Right. But this is a paper, the Gross assessments of it. 4 Q And did you review Dr. Gross's 4 paper was a paper that was where Dr. Gross was 5 5 assessment? specifically retained by industry members of the б 6 CF -- CTFA. That's a little bit different than A I don't believe so. 7 Q Okay. So just we're -- so we're clear, 7 those other 30 papers, would you agree? 8 that study was in the early '90s, correct? 8 A It is, yes. 9 A Yes. 9 Q Okay. And so are you -- are you telling 10 10 Q And it -- it may or may not have -- have us that you looked at the Gross paper, reading it had an effect on Dr. Gross's ultimate conclusions, quickly with the same care that you did with the 11 11 other more -- now more than 30 papers? 12 correct? 12 13 MR. LOCKE: Objection. 13 MR. LOCKE: Objection. If you have a THE WITNESS: I mean, I don't recall question about the Gross paper, ask the question. 14 14 15 It's not a memory test. If you want to give her 15 that it did because it's not ovarian cancer. 16 It's -- it's -- the NTP study is an inhalation, 16 the paper, go ahead. 17 and it had to do with lung cancer and it was 17 BY MR. GOLOMB: 18 discussed at length at the ISRTP. So, I'm not 18 Q Can you answer my question? 19 sure that -- Dr. Gross, I believe, was doing on 19 A Yeah, I'm happy to look at it, because 20 ovarian cancer. 20 again --21 BY MR. GOLOMB: 21 Q Well, it's not a memory test. I'm just 22 Q Okay. Is that something you're 22 trying to -- my question is a very specific one surmising, or is that something that you reviewed about the -- not about the content of the paper 2.3 23 24 from the records? 24 but about the care in which you read the paper. 25 A I'm trying to remember about Dr. Gross's 25 MR. LOCKE: What difference does it Page 741 Page 743 1 review, but those are two very separate issues, 1 make? 2 so --2 MR. GOLOMB: Well, that's rhetorical. 3 Q Okay. Well -- all right. Have you --3 THE WITNESS: Your question --MR. GOLOMB: I'm not here to answer you have -- prior to preparing for your 4 4 5 deposition, did you -- did you review the Gross 5 questions. 6 paper? 6 THE WITNESS: Your question, I thought, 7 A I reviewed -- I mean, by reviewed it --7 was about NTP bioassay, which was an inhalation 8 8 assay looking at where lung tumors were found. Q Read it. 9 A Read it quickly. I mean, there were 9 The Gross paper was about ovarian cancer. So I --10 drafts, and I -- I looked at it, and I -- I'm 10 I don't think it's in there, but if you want to 11 recalling them as being ovarian cancer. 11 show me the paper and -- where that was opined on 12 Q Okay. And did you read it in 12 as well, maybe it was. I -- I just don't 13 preparation for your deposition? 13 remember. 14 A I read it quickly. 14 BY MR. GOLOMB: Q Okay. When you say "read it quickly," 15 15 Q All right. Well, you -- you said, and what does that mean? when I refer to "you," I'm referring to the CTFA, 16 16 A I just mean there's a ton of papers out because you may not have been around at that 17 17 18 there, and I certainly am not claiming to -- as I 18 point. 19 sit here, that I read each and every one and could 19 A I wasn't. 20 recall the details of them. 20 Q But the -- the draft -- in answer to 21 Q Well, there's -- there's a ton of 21 Mr. Tisi's question earlier today, the draft of 22 papers, and I think we -- we've already talked 22 the -- the Gross paper was circulated amongst the 23 about the numbers. There are now in excess of 30 23 industry members of the CTFA, correct? 24 papers that were -- were written by -- by various A That's correct. 24 25 scientists to look at the association between talc 25 Q Right. And then it was reviewed by the

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Page 744 Page 746 Q Okay. Well, we -- we've already --CTFA members, and the CTFA members then forwarded 1 1 2 comments. Correct? 2 we've already gone through and -- and have agreed 3 A I presume so. I didn't -- have not seen 3 that the consultant is hired, the consultant is 4 4 given marching orders on what to do, the those comments. 5 5 Q Okay. Let's take a look at the next consultant goes out and does it. The consultant 6 exhibit. 6 then circulates the paper, whether it goes 7 MR. LOCKE: Why don't we take a break. 7 directly to an industry member, as it did in this 8 8 We've been going for an hour and -case, or to the CTFA. It's then circulated to all MR. GOLOMB: Sure. 9 9 the industry members, they edit it. 10 MR. LOCKE: -- almost 50 minutes. I 10 Am I -- do I have it correct so far? 11 11 think we've got about 44 minutes left. MR. LOCKE: Objection to form. 12 MR. GOLOMB: Okay. 12 THE WITNESS: Well, I mean, they 13 THE VIDEOGRAPHER: The time is 4:38 p.m. 13 would -- I wouldn't say they edit it. They can 14 We're going off the record. 14 comment on it, and then CTFA -- generally the CTFA 15 (Recess.) liaison person or PCPC would compile comments, if 15 16 THE VIDEOGRAPHER: The time is 4:49 16 that makes sense. p.m., and we're back on the record. 17 17 BY MR. GOLOMB: 18 BY MR. GOLOMB: 18 Q Okay. And would those comments include 19 Q So we were -- we were talking about the 19 telling the scientists include this or don't NTP inhalation study. And correct me if I'm 20 20 include that? 21 wrong, you -- you testified that they -- as far as 21 A I mean, in general, no. I mean, if they 22 you know, there would be no reason for that study 22 left off a -- didn't include a paper, for example, 23 to be included in the paper and analyzed within 23 or something like that, it could be a -- you know, 24 the paper. 24 did you mean to exclude this paper or something 25 Am I summarizing your testimony 25 like that, but I -- but in general --Page 745 Page 747 1 correctly? 1 Q What about -- what about the other --2 A As I recall, the --2 the vice versa of that, where they included a 3 MR. LOCKE: Objection. 3 paper and would an industry member say, Huh-uh, 4 4 THE WITNESS: The Gross paper, because take that one out? 5 5 it dealt with ovarian, and the -- and the NTP was A Not -- I mean, not to better the 6 inhalation lung cancer issue. 6 results. You know, only if they included some 7 BY MR. GOLOMB: 7 topic that seemed really off topic. But, again, 8 8 we're choosing our consultants carefully, so we Q Okay. So then I assume that there 9 would -- then there wouldn't be any reason -- and 9 don't think that's going to happen. 10 based on what you told us before about kind of the 10 Q Okay. But if -- but if that did happen, 11 subjects, how subjects are treated within a paper, 11 that would be a problem, wouldn't it? 12 and typographical or grammatical errors are edited 12 A If something were like poorly written or 13 or whatnot, there wouldn't be any reason for an 13 something, I mean, you could see where, of course, 14 industry member to tell the scientists what to 14 you could have a comment, but then you would have 15 include in the paper, would there? 15 chosen your consultant wrong. 16 A You're talking about a consulting 16 Q Okay. But if -- if -- okay. And if -- but if the consultant was 17 scientist? 17 18 said -- told by an industry member, Include this 18 Q Yeah. A And would industry -- I mean, we would 19 but don't include that --19 20 obviously up front say, This is what we want you 20 21 to review. 21 Q -- you would see an ethical problem in 22 22 that if that happened? Q Right. 23 A Or whatever -- whatever they're 23 A Correct. I mean --24 preparing it on. So I'm not sure what you mean by 24 MR. LOCKE: Objection. Beyond the 25 tell them --25 scope.

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Page 748 Page 750 THE WITNESS: Right. If they're looking 1 1 the FDA to see the results of an animal study? 2 at a topic, then they -- we would be hiring them 2 A Well, I think --3 for their expertise, and they would be selecting 3 MR. LOCKE: Same objection. 4 what -- what's relevant. 4 THE WITNESS: -- the FDA knows the 5 5 MR. GOLOMB: Okay. Can I have the next results of the animal study. That's not a 6 6 mystery. I think this is a publication, which document, please. 7 (Exhibit No. 84 was marked for 7 perhaps read poorly because it went over into 8 8 another totally different area. Nothing to do identification.) 9 BY MR. GOLOMB: 9 with ovarian cancer, nothing to do with 10 10 O This is Exhibit 84. epidemiology study. 11 This is a letter dated May 5th, 1994, 11 BY MR. GOLOMB: from Michael Chudkowski. Have you seen that 12 12 Q Okay. So you never talked to 13 letter before? 13 Mr. Chudkowski about this, correct? 14 A I don't think so. A No. 14 Q So this is a letter on Johnson & Johnson 15 Q And you've never talked to Dr. Gross 15 16 stationery dated May 4th, 1994, from Dr. Alan 16 about this? 17 Gross -- I mean to Dr. Alan Gross from --17 A No. 18 MS. FRAZIER: Do you have a copy of 18 Q So what -- you're surmising that they --19 he -- doctor -- Mr. Chudkowski wants to take the that? 19 20 (A discussion was held off the record.) 20 rodent study out of the paper because it's saving 21 BY MR. GOLOMB: 21 the FDA time --22 Q -- from Michael Chudkowski, manager of 22 MR. LOCKE: Object -preclinical evaluations. Do you see that? 23 23 BY MR. GOLOMB: 24 A To Michael Chudkowski. 24 Q -- because they already know about it? 25 Q Do you see the signature line on the 25 MR. LOCKE: Objection. There's no Page 749 Page 751 1 bottom of the page? 1 evidence that CTFA saw this at this time. 2 A Yes, I do. 2 THE WITNESS: And I -- I mean, the Gross 3 Q Okay. So it's a letter from Chudkowski 3 paper is not -- I mean, it's being published in a journal. I -- I -- this is why I was asking 4 to Gross, correct? 4 5 5 because I was confused why two, so different A Yes. 6 Q And on the second full paragraph, it 6 topics were in the same paper, and it sounded like 7 7 says: "Prior to submission, however, please that was -- that it read that it would be better 8 delete any reference to the NTP inhalation studies 8 to have a focus of your paper. 9 conducted in rodents." 9 BY MR. GOLOMB: 10 Did I read that correctly? 10 Q Okay. So the -- but the -- but the Gross paper is being sent to the FDA, and Mr. Tisi A You did. And the reason for that would 11 11 12 be this is a paper -- this is exactly what I was 12 went through it in great detail this morning, went saying, that it's on ovarian cancer and talc to the -- to the FDA to defend the industry 13 13 14 exposure, that's humans. Apparently he included 14 members against the Citizens Petition, which -an inhalation study in rodents. That's really off 15 15 which showed a -- which showed evidence of an topic. So it's probably -- it doesn't -- it's not 16 16 association between talc and ovarian cancer, relevant to the conclusion related to ovarian 17 17 correct? 18 18 cancer and talc exposure. MR. LOCKE: Objection. Q Well, so you're -- you're saying that 19 THE WITNESS: I'm not aware the Gross 19 paper went to the FDA. That was the Huncharek and 20 only the clinical aspect would be relevant to, in 20 this case, the FDA who is looking at a -- at a 21 21 Muscat document. 22 Citizens Petition rather than some animal study? 22 BY MR. GOLOMB: Q Okay. What was the purpose of the 23 MR. LOCKE: Objection. Form. 23 24 Gross --BY MR. GOLOMB: 24 25 Q You don't think it would be relevant for A This was -- this was a publication. It

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	Page 752		Page 754
1	was being published in the peer-reviewed	1	A It could mean, or it could mean no,
2	literature.	2	here it is. "Review and be prepared to discuss at
3	Q By by industry members?	3	a meeting."
4	A It was industry sponsored, yes.	4	Q At the
5	Q Right. And so prior to the and I'm	5	A At an in-person meeting.
6	reading this again: "Prior to submission,	6	Q At the January 18th, 1995 meeting of the
7	however, please delete any reference to the NTP	7	task force, correct?
8	inhalation study conducted in rodents."	8	A Yes.
9	That's what it says, correct?	9	Q And where underneath where it says
10	A Correct. Because I think they were	10	"Requires Action," it says: "The attached draft
11	asked to do a paper on ovarian cancer and talc	11	document," and that is the report from is that
12	exposure.	12	what paper is this referring to?
13	Q Okay. And so are in vitro or in vivo	13	A That's I would ask you that. I'm not
14	studies irrelevant to the analysis of the	14	sure.
15	association between talc and ovarian cancer?	15	Q Okay.
16	A I think it's a different topic, and I	16	A I mean, this is the earlier
17	think again, I'm kind of speculating here, but	17	Q This is 1994.
18	I think this was a paper that was focused on	18	A Right.
19	ovarian cancer cancer and talc exposure.	19	Q This is the same time period in which we
20	Q In any event, Mr. Chudkowski, the	20	were talking about Dr. Gross's paper.
21	manager of preclinical evaluations from Johnson &	21	A Right.
22	Johnson, was essentially telling Dr. Gross to	22	MR. LOCKE: Wait. This is 1995.
23	delete any reference to the NTP inhalation in this	23	MR. GOLOMB: 19 January 11th, 1995.
24	letter, correct?	24	The previous document that we just referred to was
25	A Because it was a very different	25	1994.
	Page 753		Page 755
1	MR. LOCKE: Objection. Lack of	1	MR. LOCKE: May 5th, 1994.
2	foundation, beyond the scope.		
3		2	
	· · · · · · · · · · · · · · · · · · ·	2 3	MR. GOLOMB: Okay.
	MS. FRAZIER: Join.	3	MR. GOLOMB: Okay. BY MR. GOLOMB:
4	MS. FRAZIER: Join. THE WITNESS: a very different type	3 4	MR. GOLOMB: Okay. BY MR. GOLOMB: Q So, in any event, this says: "Subject:
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4 5 6 7	MS. FRAZIER: Join.  THE WITNESS: a very different type of study, an animal study and an inhalation study. It's very different. BY MR. GOLOMB:	3 4 5 6 7	MR. GOLOMB: Okay. BY MR. GOLOMB: Q So, in any event, this says: "Subject: CTFA Response to Citizens Petition," correct? A Yes. Q Okay. And as you sit here today, do you
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4 5 6 7 8	MS. FRAZIER: Join.  THE WITNESS: a very different type of study, an animal study and an inhalation study. It's very different.  BY MR. GOLOMB:  Q Let me show you what's being marked as Exhibit 85.	3 4 5 6 7 8	MR. GOLOMB: Okay. BY MR. GOLOMB: Q So, in any event, this says: "Subject: CTFA Response to Citizens Petition," correct? A Yes. Q Okay. And as you sit here today, do you
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. FRAZIER: Join. THE WITNESS: a very different type of study, an animal study and an inhalation study. It's very different. BY MR. GOLOMB: Q Let me show you what's being marked as Exhibit 85. (Exhibit No. 85 was marked for identification.) BY MR. GOLOMB: Q This is a memorandum on CTFA stationery dated January 11th, 1995, to the Talc Interested Party Task Force from Stephen Gettings, director of toxicology at the CTFA. The subject is "The CTFA response to the Citizens Petition." Do you see that? A Yes. Q And this says "Requires Action." Do you see that? A Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MR. GOLOMB: Okay. BY MR. GOLOMB: Q So, in any event, this says: "Subject: CTFA Response to Citizens Petition," correct? A Yes. Q Okay. And as you sit here today, do you know who it was that wrote the response? A No. I would need to see what the attachment is. Q Okay. It says: "The attached draft document has been prepared by J&J in response to the Citizens Petition by the Cancer Prevention Coalition." Correct? A Yes. Q And then attached to that MR. LOCKE: Just for the record, this is a document that says at the bottom "1 of 8," and we only have one page. BY MR. GOLOMB: Q Which is the cover page to the memorandum that went to the members of the Talc

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	Page 756		Page 758
1	MR. LOCKE: Objection.	1	record. Completing today's videotaped session.
2	THE WITNESS: That's how I would read	2	(Whereupon, the deposition of
3	it.	3	LINDA LORETZ, Ph.D. was adjourned
4	BY MR. GOLOMB:	4	at 5:03 p.m.)
5	Q Have you seen this document before?	5	ut 2.00 p.m.)
6	A I don't know. I really need to see the	6	
7	attachment.	7	
8	Q Okay. I'm sorry, but I don't have	8	
9	copies of the attachment, but here's the draft.	9	
10	A (Peruses document.) Okay.	10	
	· · · · · · · · · · · · · · · · · · ·	l .	
11	MR. LOCKE: Since it's a J&J document,	11	
12	I'd like to send it down to their counsel just to	12	
13	see.	13	
14	BY MR. GOLOMB:	14	
15	Q It's a just to be clear, it's a	15	
16	you've now had an opportunity to see that draft,	16	
17	correct?	17	
18	A Yes.	18	
19	Q And have you seen that before?	19	
20	A I'm not sure.	20	
21	Q Okay. Did you see the the cover	21	
22	memorandum before?	22	
23	A If I had seen the cover, I would have	23	
24	seen the document, so I think I'm saying	24	
25	Q Okay. And so	25	
	Page 757		Page 759
1	A probably not, as I recall.	1	CERTIFICATE OF CERTIFIED SHORTHAND REPORTER
2	Q So to be clear, in response to what	2	The undersigned Certified Shorthand Reporter
3	· •	3	does hereby certify:
4	Mr. Locke just said, the draft is a and the	4	That the foregoing proceeding was taken before
	memorandum is a document which was produced by	5	me at the time and place therein set forth, at
5	J&J, but it's a document on CTFA letterhead,	6	_
6	correct?		which time the witness was duly sworn; That the
7	A Yes.	7	testimony of the witness and all objections made
8	Q Okay. But you haven't seen that before?	8	at the time of the examination were recorded
9	MR. LOCKE: Well, wait.	9	stenographically by me and were thereafter
10	BY MR. GOLOMB:	10	transcribed, said transcript being a true and
11	Q That you can recall as you sit here.	11	correct copy of my shorthand notes thereof; That
12	MR. LOCKE: This has a C this has a	12	the dismantling of the original transcript will
13	PCPC document and Bates number on it. So it came	13	void the reporter's certificate.
14	from PCPC's files. But it says on the cover page,	14	In witness thereof, I have subscribed my name
15	"Prepared by J&J." That's what I was referring	15	this date: October 2, 2018.
16	to.	16	
17	MR. GOLOMB: Okay. Fair enough.	17	
18	I think we're done for the day. That's	18	LESLIE A. TODD, CSR, RPR
19	the end of this subject, and we'll pick up	19	Certificate No. 5129
20	tomorrow morning.	20	
21	MR. LOCKE: Okay.	21	(The foregoing certification of
22	MR. GOLOMB: Let's go off the record,	22	this transcript does not apply to any
23	please.	23	reproduction of the same by any means,
	processor and the second secon	1	÷ * * * * * * * * * * * * * * * * * * *
24	THE VIDEOGRAPHER: The time is	24	unless under the direct control and/or

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1	INSTRUCTIONS TO WITNESS	1 ACKNOWLEDGMENT OF DEPONENT
2	Please read your deposition over carefully and	2 I,, do hereby
3	make any necessary corrections. You should state	3 certify that I have read the foregoing pages, and
4	the reason in the appropriate space on the errata	4 that the same is a correct transcription of the
5	sheet for any corrections that are made.	5 answers given by me to the questions therein
6	After doing so, please sign the errata sheet	6 propounded, except for the corrections or changes
7	and date it.	7 in form or substance, if any, noted in the
8	You are signing same subject to the changes	8 attached Errata Sheet.
9	you have noted on the errata sheet, which will be	9
10	attached to your deposition. It is imperative	10
11	that you return the original errata sheet to the	11 LINDA LORETZ, Ph.D. DATE
12	deposing attorney within thirty (30) days of	12
13	receipt of the deposition transcript by you. If	13
14	you fail to do so, the deposition transcript may	14 Subscribed and sworn to
15	be deemed to be accurate and may be used in court.	15 before me this
16		16day of,20  17 My commission expires:
17 18		17 My commission expires:
19		19 Notary Public
20		20
21		21
22		22
23		23
24		24
25		25
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3 4 5	PAGE LINE CHANGE	
6	REASON:	
8 9	REASON:	
10	REASON:	
11	ALA DOM:	
12	REASON:	
14 15	REASON:	
16	REASON:	
17		
18	REASON:	
19		
20 21	REASON:	
22 23	REASON:	
24	REASON:	

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# Exhibit 135

#### Memorandum of Meeting

Date: May 8, 2009

Place: FDA, University Station Building, College Park, MD

#### Participants:

Visitors:

John Bailey, Ph.D., Personal Care Products Council Linda Loretz, Ph.D., Personal Care Products Council Kathleen Wille, Ph.D., Johnson & Johnson David Mallon, Unilever Craig Bernard, Ph.D., Rio Tinto Minerals (via telephone) Jack Linard, Ph.D., Unilever (via telephone) Shripal Sharma, Rio Tinto Minerals (via telephone)

#### FDA:

Linda Katz, M.D., M.P.H., Meeting Chair Joshua Sharfstein, M.D.
Stephen Sundlof, D.V.M., Ph.D.
Robert Bronaugh, Ph.D.
Patricia Hansen, Ph.D.
Stanley Milstein, Ph.D.
Donald Havery
John Gasper, Minutes
Diego Rua, Ph.D.
Patrick McCarthy, Ph.D.

Subject: Talc

The meeting was held at the request of the Personal Care Products Council (PCPC). PCPC expressed their commitment to working with FDA on issues concerning cosmetic products containing talc. PCPC and the representatives of individual firms presented an analysis of the epidemiological association of cosmetic talc use with ovarian cancer, information regarding chemical and physical properties they believe differentiate cosmetic grade talc from other grades of talc, and different specifications used. FDA representatives indicated that they would like to see more detailed information on the chemical and physical properties of cosmetic grade talc, characterization and testing of cosmetic grade talc, commercial suppliers and users of cosmetic grade talc, and related information. Dr. Bailey of PCPC indicated that it might take some time to assemble all of the information, but that he would check with the members and get back to Dr. Katz on the timing. FDA representatives also indicated that if PCPC wished the Agency to consider the information in responding to citizen petitions, it should submit the information to the appropriate dockets. PCPC also indicated that they would consider



different mechanisms for strengthening the guidelines and procedures meant to assure the safety of talc used in cosmetics.

#### **Action Items:**

- o Dr. Bailey to forward PCPC's expected responses to FDA questions (see attached) as soon as possible in 2 weeks. Additionally, PCPC will provide a list of talc suppliers along with their contact information.
- PCPC agreed to submit their prepared comments on: Citizen Petition to the Commissioner of the Food and Drug Administration Seeking a Cancer Warning on Talc Products to the docket.

# Exhibit 136

## Case 3:16-md-02738-MAS-RLS Document 9895-3 Filed 05/30/19 Page 222 of 565 PageID: 71.466 YGYNO-976277; No. of pages: 3; 4

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#### Talc and ovarian cancer

Steven A. Narod \*

Women's College Research Institute, Toronto, Ontario, Canada Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada

#### HIGHLIGHTS

- Talc use has been linked to the risk of ovarian cancer in many case-control studies.
- · Genital talc use is much less common now than it was in earlier cohorts of women in North America.
- It is not possible to say that any specific case of ovarian cancer was the result of talc use.

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Interest in a possible link between talcum powder and ovarian cancer risk dates back to the 1960s when the public was concerned about asbestos contamination in talc. Talc has been in the news intermittently since then, but the story of talc and ovarian cancer made the front page in February 2016, when the family of an ovarian cancer patient successfully sued Johnson and Johnson for 72 million dollars. This surprising jury decision raises a few questions. Is there a real and robust statistical association between talc use and ovarian cancer, and if so, is the association causal or due to confounding? What is the risk of cancer associated with talc use and how do we tell if a particular case of ovarian cancer was caused by talc? What should we tell our patients?

Most of the evidence comes from case-control studies. In 2013, the Ovarian Cancer Association Consortium pooled eight of these and analysed 8525 cases and 9859 controls [1]. They reported that genital powder use was associated with a modest but significant increased risk of epithelial ovarian cancer (OR = 1.24; 95% CI 1.15–1.33). The association between talc and ovarian cancer was significant in five of the eight individual studies. More recently, Cramer et al. studied 2041 cases and 2100 controls (some of whom were included in the OCAC study) [2]. They

E-mail address: steven.narod@wchospital.ca.

estimated the risk of ovarian cancer associated with genital talc use to be 1.33 (95% CI 1.16 to 1.52) The case-control studies to date are consistent; given the small effect size it is not surprising that some are positive (i.e., show a significant increase in risk) and some are negative (i.e., show a non-significant increase in risk or no risk difference). Some say, based on this data, that there is little or no evidence that talc is associated with ovarian cancer. This is a conservative opinion, based on an uncompromising interpretation of statistics and a demand for proof. For the sake of argument, let us suppose that the true risk ratio for ever use of talc and the development of ovarian cancer is 1.2. This estimate is the one generated from the large pooling study [1] and is the level of risk that is under discussion the media. It is possible that the true risk might be lower or higher than this single estimate. In this scenario, where talc increases the risk of ovarian cancer by 20% beyond the baseline of 1.3% lifetime, it would be challenging to convince the epidemiology community that there is a danger. Simply put, a risk ratio of this size falls outside the resolution of most epidemiologic studies; for example, if we set the *p*-value for significance at 0.05, then, in order to have a power of 0.80 to discriminate an increase in risk of 20%, and if 20% of the population is exposed to talc, we would require a case-control study of 2801 cases and 2801 controls. This is a very large sample for a case-control study, especially given that ovarian cancer is rare and only but the large study of Cramer et al the pooled analyses of OCAC were designed to detect and odds ratios this small [1,2]. If the

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<sup>\*</sup> Women's College Research Institute, 76 Grenville Street, Toronto, Ontario, M5S 1B1., Canada.

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magnitude of the association is to be estimated with precision it is important that consortia are develop and expanded in order to generate the appropriate sample size.

Prospective observational studies are less prone to bias than casecontrol studies, and for this reason they are given greater weight. In particular, they are not prone to recall bias (where the accuracy of the recollection of the exposure differs between cases and controls); selection bias (where the unexposed and exposed women are not equally likely to be ascertained for study) and survivorship bias (which would occur if the survival of women with ovarian cancer differs, depending on prior talc exposure. In the Nurses Health Study, 78,630 women were followed for a mean of 12.9 years [3]. There were 307 ovarian cancers diagnosed in the follow-up period. There was no overall association with ever-use of talc (HR = 1.09; 95% CI 0.86 to 1.37, but there was a modest and significant increased risk for serous ovarian cancer (HR = 1.40; 95% CI; 1.02-1.91). These figures could be dismissed as non-significant or as due to chance, but if the real risk were in fact 1.2, this is about what we would expect. In the Women's Health Initiative [4], 61,285 women were followed for an average of 12.4 years. 53% of the women reported perineal talc use (a very high proportion). The adjusted hazard ratio for serous ovarian cancer was 1.13, but this was not significant (95% CI 0.84 to 1.51). Neither prospective study confirmed the association of talc use and ovarian cancer raised by the case-control studies, but neither study was powered to detect a risk of 1.2 and therefore we cannot exclude the possibility. Only two women in a thousand will develop ovarian cancer in a ten-year follow up period. If we study 10,000 women over 10 years we can expect 20 cancers to occur. If the true odds ratio is 1.2, we will expect 20 cancers in an unexposed group of 10,000 women and 24 cancers in an exposed group of equal size and this difference will not be significant (p = 0.65). In order to achieve statistical significance in a prospective study, we need a much larger cohort, e.g., we will need to study upwards of 200,000 women for ten years.

Given this inherent limitation of cohort studies, it is not surprising that we have not been able to confirm the case-control studies with prospective studies, but this does not mean that the case-control studies were wrong. I don't think it is because the prospective studies are free from the biases that plague the case-control studies (e.g., recall bas) — I think the parsimonious explanation is that they lack statistical power. It is well that we also consider various possible biases as a source of imprecision in case-control studies. In the case of talc and ovarian cancer we should consider recall bias, survivorship bias and confounding bias. The idea behind recall bias is that a case is more likely to (correctly) recall the past use of talc than a control (who might forget) or that a case is more likely than a control to (incorrectly) report the use of talc that was never used. In studies where simple exposures that are coded as never/ ever use recall bias unlikely to be an important source of bias. Survivorship bias would occur if we used prevalent cases and the use of talc was associated with better or worse survival, once ovarian cancer develops. There is no reason to assume that this is the case.

Confounding bias may be more subtle. When people say that 'association is not causality' they mean to say that that talc may not actually cause ovarian cancer but both talc and ovarian cancer may be linked to a third factor such as birth control pills — perhaps women who use talc are less likely to use birth control pills and therefore form a high risk group. Hardly likely — and the other risk factors for ovarian cancer are parity, breast feeding and tubal ligation. None of these are a priori likely to be confounders and in any case, most case-control studies will adjust for these. The most important potential confounder is year of birth (see below) and it is critical to control for this. It is unlikely that the association between talc and ovarian cancer is due to confounding and so it is fair to say that if there is a statistically robust relationship between talc use and ovarian cancer it is likely to be causal (albeit with intermediate factors such as inflammation). In any case, given the number of hazard ratios reported in the literature between 1.1 of 1.4 in both case-control and cohort studies, it is disingenuous to state that there is no evidence that talc is associated with ovarian cancer.

It has been suggested that talc passes through the cervix and endometrium and becomes lodged in the fallopian tube where it induces an inflammatory reaction [5]. This is hypothetical, but is supported by the observation of talc particles within the pelvic organs [6] and fits with the paradigm that most serous ovarian cancers originate in the fallopian tube and that intra-epithelial lesions in the fallopian epithelium are the earliest manifestations of an impending ovarian cancer [7]. If the model is correct, it is possible that the passage of talc is aided by retrograde menses and that talc use during menses poses a special risk. This might explain in part why the association between talc applied to sanitary napkins and ovarian cancer is among the most consistent. Against the model is the observation that, in the prospective studies, the relative risk of cancer associated with talc was not lower in women who had a tubal ligation [3,4] (and presumably had blocked access to talc).

If we accept that the actual hazard ratio for ever-use versus neveruse is 1.2 how are we to interpret this number? If we consider a particular woman who uses talc regularly, her lifetime risk of ovarian cancer would increase from about 1.3% to 1.6%, an increase of 0.3% or three cases in a thousand. On a yearly scale, the risk rises from 20 per 100,000 women per year to 24 per 100,000 per year or four cancer cases for every 100,000 talc users. The latter might strike as more favorable, but, in fact describes the same risk. If we consider the population as a whole, the total number of ovarian cancer cases caused by talc depends on the frequency of talc use in the population. It is right to be concerned over the carcinogenicity of talc even if the risk ratio is low, because up to 50% of women are exposed [1]. If 40% of women use talc and the relative risk is 1.2, then 7% of ovarian cancer cases would be attributable to talc use or 1577 cases a year in the USA. This is not a trivial number and should not be dismissed. If 20% of women were talc users the number of cases per year would be 819. If only 5% of women use talc then the number of cases per year would be 211. Few perhaps, but if ovarian cancer is avoidable, it is best avoided. Is there a downside? Talc affords comfort and was used commonly in the past to control moisture and odor but women have many more choices nowadays. One could of course make a recommendation here not to use talc on sanitary napkins, but this will have little impact because few women continue to use it. In our database of 6000 women from North America that we follow at Women's College Hospital, the use of talc on sanitary napkins has declined precipitously from one generation to the next; talc use was recorded by 11% for women born from 1920 to 1940, but for only 1% of women born after 1975. Similarly, the use of talc applied directly to the genital area fell from 19% to 3% over the same period.

In the interests of public health, I believe we should caution women against using genital talcum powder. However, this policy of talc avoidance is unlikely to have much impact nowadays given this downward trend in usage. I don't think we should try to ascribe any particular case of ovarian cancer to prior talc use. The estimate of a risk ratio of 1.2 provides information about the potential contribution of talc to the burden of ovarian cancer in the population, but is not helpful in determining if a specific case is, or is not, the result of talc exposure. Are we able to make helpful recommendations for women who have used it in the past but who no longer use it? Probably not, we do not offer preventive surgery for women with a risk of ovarian cancer that is less than 2% and screening with CA125 or ultrasound is not recommended to women at average or slightly increased risk.

#### **Conflict of interest**

The author declares no conflict of interest.

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### Moving to a World Beyond "p < 0.05"

Ronald L. Wasserstein, Allen L. Schirm & Nicole A. Lazar

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#### **EDITORIAL**

**3** OPEN ACCESS



#### Moving to a World Beyond "p < 0.05"

Some of you exploring this special issue of *The American Statistician* might be wondering if it's a scolding from pedantic statisticians lecturing you about what *not* to do with *p*-values, without offering any real ideas of what *to do* about the very hard problem of separating signal from noise in data and making decisions under uncertainty. Fear not. In this issue, thanks to 43 innovative and thought-provoking papers from forward-looking statisticians, help is on the way.

#### 1. "Don't" Is Not Enough

There's not much we can say here about the perils of *p*-values and significance testing that hasn't been said already for decades (Ziliak and McCloskey 2008; Hubbard 2016). If you're just arriving to the debate, here's a sampling of what not to do:

- Don't base your conclusions solely on whether an association or effect was found to be "statistically significant" (i.e., the p-value passed some arbitrary threshold such as p < 0.05).
- Don't believe that an association or effect exists just because it was statistically significant.
- Don't believe that an association or effect is absent just because it was not statistically significant.
- Don't believe that your p-value gives the probability that chance alone produced the observed association or effect or the probability that your test hypothesis is true.
- Don't conclude anything about scientific or practical importance based on statistical significance (or lack thereof).

Don't. Don't. Just...don't. Yes, we talk a lot about don'ts. The ASA Statement on p-Values and Statistical Significance (Wasserstein and Lazar 2016) was developed primarily because after decades, warnings about the don'ts had gone mostly unheeded. The statement was about what not to do, because there is widespread agreement about the don'ts.

Knowing what not to do with *p*-values is indeed necessary, but it does not suffice. It is as though statisticians were asking users of statistics to tear out the beams and struts holding up the edifice of modern scientific research without offering solid construction materials to replace them. Pointing out old, rotting timbers was a good start, but now we need more.

Recognizing this, in October 2017, the American Statistical Association (ASA) held the Symposium on Statistical Inference, a two-day gathering that laid the foundations for this

special issue of *The American Statistician*. Authors were explicitly instructed to develop papers for the variety of audiences interested in these topics. If you use statistics in research, business, or policymaking but are not a statistician, these articles were indeed written with YOU in mind. And if you are a statistician, there is still much here for you as well.

The papers in this issue propose many new ideas, ideas that in our determination as editors merited publication to enable broader consideration and debate. The ideas in this editorial are likewise open to debate. They are our own attempt to distill the wisdom of the many voices in this issue into an essence of good statistical practice as we currently see it: some do's for teaching, doing research, and informing decisions.

Yet the voices in the 43 papers in this issue do not sing as one. At times in this editorial and the papers you'll hear deep dissonance, the echoes of "statistics wars" still simmering today (Mayo 2018). At other times you'll hear melodies wrapping in a rich counterpoint that may herald an increasingly harmonious new era of statistics. To us, these are all the sounds of statistical inference in the 21st century, the sounds of a world learning to venture beyond "p < 0.05."

This is a world where researchers are free to treat "p=0.051" and "p=0.049" as not being categorically different, where authors no longer find themselves constrained to selectively publish their results based on a single magic number. In this world, where studies with "p<0.05" and studies with "p>0.05" are not automatically in conflict, researchers will see their results more easily replicated—and, even when not, they will better understand *why*. As we venture down this path, we will begin to see fewer false alarms, fewer overlooked discoveries, and the development of more customized statistical strategies. Researchers will be free to communicate all their findings in all their glorious uncertainty, knowing their work is to be judged by the quality and effective communication of their science, and not by their p-values. As "statistical significance" is used less, statistical thinking will be used more.

The ASA Statement on P-Values and Statistical Significance started moving us toward this world. As of the date of publication of this special issue, the statement has been viewed over 294,000 times and cited over 1700 times—an average of about 11 citations per week since its release. Now we must go further. That's what this special issue of *The American Statistician* sets out to do.

To get to the do's, though, we must begin with one more don't.

#### 2. Don't Say "Statistically Significant"

The ASA Statement on P-Values and Statistical Significance stopped just short of recommending that declarations of "statistical significance" be abandoned. We take that step here. We conclude, based on our review of the articles in this special issue and the broader literature, that it is time to stop using the term "statistically significant" entirely. Nor should variants such as "significantly different," "p < 0.05," and "nonsignificant" survive, whether expressed in words, by asterisks in a table, or in some other way.

Regardless of whether it was ever useful, a declaration of "statistical significance" has today become meaningless. Made broadly known by Fisher's use of the phrase (1925), Edgeworth's (1885) original intention for statistical significance was simply as a tool to indicate when a result warrants further scrutiny. But that idea has been irretrievably lost. Statistical significance was never meant to imply scientific importance, and the confusion of the two was decried soon after its widespread use (Boring 1919). Yet a full century later the confusion persists.

And so the tool has become the tyrant. The problem is not simply use of the word "significant," although the statistical and ordinary language meanings of the word are indeed now hopelessly confused (Ghose 2013); the term should be avoided for that reason alone. The problem is a larger one, however: using bright-line rules for justifying scientific claims or conclusions can lead to erroneous beliefs and poor decision making (ASA statement, Principle 3). A label of statistical significance adds nothing to what is already conveyed by the value of p; in fact, this dichotomization of p-values makes matters worse.

For example, no *p*-value can reveal the plausibility, presence, truth, or importance of an association or effect. Therefore, a label of statistical significance does not mean or imply that an association or effect is highly probable, real, true, or important. Nor does a label of statistical nonsignificance lead to the association or effect being improbable, absent, false, or unimportant. Yet the dichotomization into "significant" and "not significant" is taken as an imprimatur of authority on these characteristics. In a world without bright lines, on the other hand, it becomes untenable to assert dramatic differences in interpretation from inconsequential differences in estimates. As Gelman and Stern (2006) famously observed, the difference between "significant" and "not significant" is not itself statistically significant.

Furthermore, this false split into "worthy" and "unworthy" results leads to the selective reporting and publishing of results based on their statistical significance—the so-called "file drawer problem" (Rosenthal 1979). And the dichotomized reporting problem extends beyond just publication, notes Amrhein, Trafimow, and Greenland (2019): when authors use p-value thresholds to select which findings to discuss in their papers, "their conclusions and what is reported in subsequent news and reviews will be biased...Such selective attention based on study outcomes will therefore not only distort the literature but will slant published descriptions of study results—biasing the summary descriptions reported to practicing professionals and the general public." For the integrity of scientific publishing and research dissemination, therefore, whether a p-value passes any arbitrary threshold should not be considered at all when deciding which results to present or highlight.

To be clear, the problem is not that of having only two labels. Results should not be trichotomized, or indeed categorized into any number of groups, based on arbitrary *p*-value thresholds. Similarly, we need to stop using confidence intervals as another means of dichotomizing (based, on whether a null value falls within the interval). And, to preclude a reappearance of this problem elsewhere, we must not begin arbitrarily categorizing other statistical measures (such as Bayes factors).

Despite the limitations of p-values (as noted in Principles 5 and 6 of the ASA statement), however, we are not recommending that the calculation and use of continuous p-values be discontinued. Where p-values are used, they should be reported as continuous quantities (e.g., p=0.08). They should also be described in language stating what the value means in the scientific context. We believe that a reasonable prerequisite for reporting any p-value is the ability to interpret it appropriately. We say more about this in Section 3.3.

To move forward to a world beyond "p < 0.05," we must recognize afresh that statistical inference is not—and never has been—equivalent to scientific inference (Hubbard, Haig, and Parsa 2019; Ziliak 2019). However, looking to statistical significance for a marker of scientific observations' credibility has created a guise of equivalency. Moving beyond "statistical significance" opens researchers to the real significance of statistics, which is "the science of learning from data, and of measuring, controlling, and communicating uncertainty" (Davidian and Louis 2012).

In sum, "statistically significant"—don't say it and don't use it.

#### 3. There Are Many Do's

With the don'ts out of the way, we can finally discuss ideas for specific, positive, constructive actions. We have a massive list of them in the seventh section of this editorial! In that section, the authors of all the articles in this special issue each provide their own short set of do's. Those lists, and the rest of this editorial, will help you navigate the substantial collection of articles that follows.

Because of the size of this collection, we take the liberty here of distilling our readings of the articles into a summary of what can be done to move beyond "p < 0.05." You will find the rich details in the articles themselves.

What you will NOT find in this issue is one solution that majestically replaces the outsized role that statistical significance has come to play. The statistical community has not yet converged on a simple paradigm for the use of statistical inference in scientific research—and in fact it may never do so. A one-size-fits-all approach to statistical inference is an inappropriate expectation, even after the dust settles from our current remodeling of statistical practice (Tong 2019). Yet solid principles for the use of statistics do exist, and they are well explained in this special issue.

We summarize our recommendations in two sentences totaling seven words: "Accept uncertainty. Be thoughtful, open, and modest." Remember "ATOM."

#### 3.1. Accept Uncertainty

Uncertainty exists everywhere in research. And, just like with the frigid weather in a Wisconsin winter, there are those who will flee from it, trying to hide in warmer havens elsewhere. Others, however, accept and even delight in the omnipresent cold; these are the ones who buy the right gear and bravely take full advantage of all the wonders of a challenging climate. Significance tests and dichotomized p-values have turned many researchers into scientific snowbirds, trying to avoid dealing with uncertainty by escaping to a "happy place" where results are either statistically significant or not. In the real world, data provide a noisy signal. Variation, one of the causes of uncertainty, is everywhere. Exact replication is difficult to achieve. So it is time to get the right (statistical) gear and "move toward a greater acceptance of uncertainty and embracing of variation" (Gelman

Statistical methods do not rid data of their uncertainty. "Statistics," Gelman (2016) says, "is often sold as a sort of alchemy that transmutes randomness into certainty, an 'uncertainty laundering' that begins with data and concludes with success as measured by statistical significance." To accept uncertainty requires that we "treat statistical results as being much more incomplete and uncertain than is currently the norm" (Amrhein, Trafimow, and Greenland 2019). We must "countenance uncertainty in all statistical conclusions, seeking ways to quantify, visualize, and interpret the potential for error" (Calin-Jageman and Cumming 2019).

"Accept uncertainty and embrace variation in effects," advise McShane et al. in Section 7 of this editorial. "[W]e can learn much (indeed, more) about the world by forsaking the false promise of certainty offered by dichotomous declarations of truth or falsity—binary statements about there being 'an effect' or 'no effect'—based on some p-value or other statistical threshold being attained."

We can make acceptance of uncertainty more natural to our thinking by accompanying every point estimate in our research with a measure of its uncertainty such as a standard error or interval estimate. Reporting and interpreting point and interval estimates should be routine. However, simplistic use of confidence intervals as a measurement of uncertainty leads to the same bad outcomes as use of statistical significance (especially, a focus on whether such intervals include or exclude the "null hypothesis value"). Instead, Greenland (2019) and Amrhein, Trafimow, and Greenland (2019) encourage thinking of confidence intervals as "compatibility intervals," which use *p*-values to show the effect sizes that are most compatible with the data under the given model.

How will accepting uncertainty change anything? To begin, it will prompt us to seek better measures, more sensitive designs, and larger samples, all of which increase the rigor of research. It also helps us **be modest** (the fourth of our four principles, on which we will expand in Section 3.4) and encourages "metaanalytic thinking" (Cumming 2014). Accepting uncertainty as inevitable is a natural antidote to the seductive certainty falsely promised by statistical significance. With this new outlook, we will naturally seek out replications and the integration of evidence through meta-analyses, which usually requires point and interval estimates from contributing studies. This will in turn give us more precise overall estimates for our effects and associations. And this is what will lead to the best research-based guidance for practical decisions.

Accepting uncertainty leads us to be thoughtful, the second of our four principles.

#### 3.2. Be Thoughtful

What do we mean by this exhortation to "be thoughtful"? Researchers already clearly put much thought into their work. We are not accusing anyone of laziness. Rather, we are envisioning a sort of "statistical thoughtfulness." In this perspective, statistically thoughtful researchers begin above all else with clearly expressed objectives. They recognize when they are doing exploratory studies and when they are doing more rigidly pre-planned studies. They invest in producing solid data. They consider not one but a multitude of data analysis techniques. And they think about so much more.

#### 3.2.1. Thoughtfulness in the Big Picture

"[M]ost scientific research is exploratory in nature," Tong (2019) contends. "[T]he design, conduct, and analysis of a study are necessarily flexible, and must be open to the discovery of unexpected patterns that prompt new questions and hypotheses. In this context, statistical modeling can be exceedingly useful for elucidating patterns in the data, and researcher degrees of freedom can be helpful and even essential, though they still carry the risk of overfitting. The price of allowing this flexibility is that the validity of any resulting statistical inferences is undermined."

Calin-Jageman and Cumming (2019) caution that "in practice the dividing line between planned and exploratory research can be difficult to maintain. Indeed, exploratory findings have a slippery way of 'transforming' into planned findings as the research process progresses." At the bottom of that slippery slope one often finds results that don't reproduce.

Anderson (2019) proposes three questions thoughtful researchers asked thoughtful researchers evaluating research results: What are the practical implications of the estimate? How precise is the estimate? And is the model correctly specified? The latter question leads naturally to three more: Are the modeling assumptions understood? Are these assumptions valid? And do the key results hold up when other modeling choices are made? Anderson further notes, "Modeling assumptions (including all the choices from model specification to sample selection and the handling of data issues) should be sufficiently documented so independent parties can critique, and replicate, the work."

Drawing on archival research done at the Guinness Archives in Dublin, Ziliak (2019) emerges with ten "G-values" he believes we all wish to maximize in research. That is, we want large Gvalues, not small p-values. The ten principles of Ziliak's "Guinnessometrics" are derived primarily from his examination of experiments conducted by statistician William Sealy Gosset while working as Head Brewer for Guinness. Gosset took an economic approach to the logic of uncertainty, preferring balanced designs over random ones and estimation of gambles over bright-line "testing." Take, for example, Ziliak's G-value 10: "Consider purpose of the inquiry, and compare with best

practice," in the spirit of what farmers and brewers must do. The purpose is generally NOT to falsify a null hypothesis, says Ziliak. Ask what is at stake, he advises, and determine what magnitudes of change are humanly or scientifically meaningful in context.

Pogrow (2019) offers an approach based on practical benefit rather than statistical or practical significance. This approach is especially useful, he says, for assessing whether interventions in complex organizations (such as hospitals and schools) are effective, and also for increasing the likelihood that the observed benefits will replicate in subsequent research and in clinical practice. In this approach, "practical benefit" recognizes that reliance on small effect sizes can be as problematic as relying on p-values.

**Thoughtful research** prioritizes sound data production by putting energy into the careful planning, design, and execution of the study (Tong 2019).

Locascio (2019) urges researchers to be prepared for a new publishing model that evaluates their research based on the importance of the questions being asked and the methods used to answer them, rather than the outcomes obtained.

## 3.2.2. Thoughtfulness Through Context and Prior Knowledge

**Thoughtful research** considers the scientific context and prior evidence. In this regard, a declaration of statistical significance is the antithesis of thoughtfulness: it says nothing about practical importance, and it ignores what previous studies have contributed to our knowledge.

Thoughtful research looks ahead to prospective outcomes in the context of theory and previous research. Researchers would do well to ask, What do we already know, and how certain are we in what we know? And building on that and on the field's theory, what magnitudes of differences, odds ratios, or other effect sizes are practically important? These questions would naturally lead a researcher, for example, to use existing evidence from a literature review to identify specifically the findings that would be practically important for the key outcomes under study.

Thoughtful research includes careful consideration of the definition of a meaningful effect size. As a researcher you should communicate this up front, before data are collected and analyzed. Afterwards is just too late; it is dangerously easy to justify observed results after the fact and to overinterpret trivial effect sizes as being meaningful. Many authors in this special issue argue that consideration of the effect size and its "scientific meaningfulness" is essential for reliable inference (e.g., Blume et al. 2019; Betensky 2019). This concern is also addressed in the literature on equivalence testing (Wellek 2017).

**Thoughtful research** considers "related prior evidence, plausibility of mechanism, study design and data quality, real world costs and benefits, novelty of finding, and other factors that vary by research domain...without giving priority to *p*-values or other purely statistical measures" (McShane et al. 2019).

**Thoughtful researchers** "use a toolbox of statistical techniques, employ good judgment, and keep an eye on developments in statistical and data science," conclude Heck and Krueger (2019), who demonstrate how the *p*-value can be useful to researchers as a heuristic.

## 3.2.3. Thoughtful Alternatives and Complements to P-Values

**Thoughtful research** considers multiple approaches for solving problems. This special issue includes some ideas for supplementing or replacing *p*-values. Here is a short summary of some of them, with a few technical details:

Amrhein, Trafimow, and Greenland (2019) and Greenland (2019) advise that null p-values should be supplemented with a p-value from a test of a pre-specified alternative (such as a minimal important effect size). To reduce confusion with posterior probabilities and better portray evidential value, they further advise that p-values be transformed into s-values (Shannon information, surprisal, or binary logworth)  $s = -\log_2(p)$ . This measure of evidence affirms other arguments that the evidence against a hypothesis contained in the p-value is not nearly as strong as is believed by many researchers. The change of scale also moves users away from probability misinterpretations of the p-value.

Blume et al. (2019) offer a "second generation p-value (SGPV)," the characteristics of which mimic or improve upon those of *p*-values but take practical significance into account. The null hypothesis from which an SGPV is computed is a composite hypothesis representing a range of differences that would be practically or scientifically inconsequential, as in equivalence testing (Wellek 2017). This range is determined in advance by the experimenters. When the SGPV is 1, the data only support null hypotheses; when the SGPV is 0, the data are incompatible with any of the null hypotheses. SGPVs between 0 and 1 are inconclusive at varying levels (maximally inconclusive at or near SGPV = 0.5.) Blume et al. illustrate how the SGPV provides a straightforward and useful descriptive summary of the data. They argue that it eliminates the problem of how classical statistical significance does not imply scientific relevance, it lowers false discovery rates, and its conclusions are more likely to reproduce in subsequent studies.

The "analysis of credibility" (AnCred) is promoted by Matthews (2019). This approach takes account of both the width of the confidence interval and the location of its bounds when assessing weight of evidence. AnCred assesses the credibility of inferences based on the confidence interval by determining the level of prior evidence needed for a new finding to provide credible evidence for a nonzero effect. If this required level of prior evidence is supported by current knowledge and insight, Matthews calls the new result "credible evidence for a non-zero effect," irrespective of its statistical significance/nonsignificance.

Colquhoun (2019) proposes continuing the use of continuous *p*-values, but only in conjunction with the "false positive risk (FPR)." The FPR answers the question, "If you observe a 'significant' *p*-value after doing a single unbiased experiment, what is the probability that your result is a false positive?" It tells you what most people mistakenly still think the *p*-value does, Colquhoun says. The problem, however, is that to calculate the FPR you need to specify the prior probability that an effect is real, and it's rare to know this. Colquhoun suggests that the FPR could be calculated with a prior probability of 0.5, the largest value reasonable to assume in the absence of hard prior data. The FPR found this way is in a sense the minimum false positive risk (mFPR); less plausible hypotheses (prior probabilities below 0.5) would give even bigger FPRs, Colquhoun says, but the

mFPR would be a big improvement on reporting a *p*-value alone. He points out that p-values near 0.05 are, under a variety of assumptions, associated with minimum false positive risks of 20-30%, which should stop a researcher from making too big

a claim about the "statistical significance" of such a result.

Benjamin and Berger (2019) propose a different supplement to the null p-value. The Bayes factor bound (BFB)—which under typically plausible assumptions is the value  $1/(-ep \ln p)$  represents the upper bound of the ratio of data-based odds of the alternative hypothesis to the null hypothesis. Benjamin and Berger advise that the BFB should be reported along with the continuous p-value. This is an incomplete step toward revising practice, they argue, but one that at least confronts the researcher with the maximum possible odds that the alternative hypothesis is true—which is what researchers often think they are getting with a p-value. The BFB, like the FPR, often clarifies that the evidence against the null hypothesis contained in the *p*-value is not nearly as strong as is believed by many researchers.

Goodman, Spruill, and Komaroff (2019) propose a twostage approach to inference, requiring both a small p-value below a pre-specified level and a pre-specified sufficiently large effect size before declaring a result "significant." They argue that this method has improved performance relative to use of dichotomized *p*-values alone.

Gannon, Pereira, and Polpo (2019) have developed a testing procedure combining frequentist and Bayesian tools to provide a significance level that is a function of sample size.

Manski (2019) and Manski and Tetenov (2019) urge a return to the use of statistical decision theory, which they say has largely been forgotten. Statistical decision theory is not based on pvalue thresholds and readily distinguishes between statistical and clinical significance.

Billheimer (2019) suggests abandoning inference about parameters, which are frequently hypothetical quantities used to idealize a problem. Instead, he proposes focusing on the prediction of future observables, and their associated uncertainty, as a means to improving science and decisionmaking.

#### 3.2.4. Thoughtful Communication of Confidence

Be thoughtful and clear about the level of confidence or credibility that is present in statistical results.

Amrhein, Trafimow, and Greenland (2019) and Greenland (2019) argue that the use of words like "significance" in conjunction with p-values and "confidence" with interval estimates misleads users into overconfident claims. They propose that researchers think of p-values as measuring the compatibility between hypotheses and data, and interpret interval estimates as "compatibility intervals."

In what may be a controversial proposal, Goodman (2018) suggests requiring "that any researcher making a claim in a study accompany it with their estimate of the chance that the claim is true." Goodman calls this the confidence index. For example, along with stating "This drug is associated with elevated risk of a heart attack, relative risk (RR) = 2.4, p = 0.03," Goodman says investigators might add a statement such as "There is an 80% chance that this drug raises the risk, and a 60% chance that the risk is at least doubled." Goodman acknowledges, "Although

simple on paper, requiring a confidence index would entail a profound overhaul of scientific and statistical practice."

In a similar vein, Hubbard and Carriquiry (2019) urge that researchers prominently display the probability the hypothesis is true or a probability distribution of an effect size, or provide sufficient information for future researchers and policy makers to compute it. The authors further describe why such a probability is necessary for decision making, how it could be estimated by using historical rates of reproduction of findings, and how this same process can be part of continuous "quality control" for

Being thoughtful in our approach to research will lead us to be open in our design, conduct, and presentation of it

#### 3.3. Be Open

We envision openness as embracing certain positive practices in the development and presentation of research work.

#### 3.3.1. Openness to Transparency and to the Role of **Expert Judgment**

First, we repeat oft-repeated advice: Be open to "open science" practices. Calin-Jageman and Cumming (2019), Locascio (2019), and others in this special issue urge adherence to practices such as public pre-registration of methods, transparency and completeness in reporting, shared data and code, and even pre-registered ("results-blind") review. Completeness in reporting, for example, requires not only describing all analyses performed but also presenting all findings obtained, without regard to statistical significance or any such criterion.

Openness also includes understanding and accepting the role of expert judgment, which enters the practice of statistical inference and decision-making in numerous ways (O'Hagan 2019). "Indeed, there is essentially no aspect of scientific investigation in which judgment is not required," O'Hagan observes. "Judgment is necessarily subjective, but should be made as carefully, as objectively, and as scientifically as possible."

Subjectivity is involved in any statistical analysis, Bayesian or frequentist. Gelman and Hennig (2017) observe, "Personal decision making cannot be avoided in statistical data analysis and, for want of approaches to justify such decisions, the pursuit of objectivity degenerates easily to a pursuit to merely appear objective." One might say that subjectivity is not a problem; it is part of the solution.

Acknowledging this, Brownstein et al. (2019) point out that expert judgment and knowledge are required in all stages of the scientific method. They examine the roles of expert judgment throughout the scientific process, especially regarding the integration of statistical and content expertise. "All researchers, irrespective of their philosophy or practice, use expert judgment in developing models and interpreting results," say Brownstein et al. "We must accept that there is subjectivity in every stage of scientific inquiry, but objectivity is nevertheless the fundamental goal. Therefore, we should base judgments on evidence and careful reasoning, and seek wherever possible to eliminate potential sources of bias."

How does one rigorously elicit expert knowledge and judgment in an effective, unbiased, and transparent way? O'Hagan (2019) addresses this, discussing protocols to elicit expert knowledge in an unbiased and as scientifically sound was as possible. It is also important for such elicited knowledge to be examined critically, comparing it to actual study results being an important diagnostic step.

#### 3.3.2. Openness in Communication

**Be open** in your reporting. Report *p*-values as continuous, descriptive statistics, as we explain in Section 2. We realize that this leaves researchers without their familiar bright line anchors. Yet if we were to propose a universal template for presenting and interpreting continuous *p*-values we would violate our own principles! Rather, we believe that the thoughtful use and interpretation of *p*-values will never adhere to a rigid rulebook, and will instead inevitably vary from study to study. Despite these caveats, we can offer recommendations for sound practices, as described below.

In all instances, regardless of the value taken by p or any other statistic, consider what McShane et al. (2019) call the "currently subordinate factors"—the factors that should no longer be subordinate to "p < 0.05." These include relevant prior evidence, plausibility of mechanism, study design and data quality, and the real-world costs and benefits that determine what effects are scientifically important. The scientific context of your study matters, they say, and this should guide your interpretation.

When using *p*-values, remember not only Principle 5 of the ASA statement: "A *p*-value...does not measure the size of an effect or the importance of a result" but also Principle 6: "By itself, a *p*-value does not provide a good measure of evidence regarding a model or hypothesis." Despite these limitations, if you present *p*-values, do so for more than one hypothesized value of your variable of interest (Fraser 2019; Greenland 2019), such as 0 and at least one plausible, relevant alternative, such as the minimum practically important effect size (which should be determined before analyzing the data).

Betensky (2019) also reminds us to interpret the *p*-value in the context of sample size and meaningful effect size.

Instead of p, you might consider presenting the s-value (Greenland 2019), which is described in Section 3.2. As noted in Section 3.1, you might present a confidence interval. Sound practices in the interpretation of confidence intervals include (1) discussing both the upper and lower limits and whether they have different practical implications, (2) paying no particular attention to whether the interval includes the null value, and (3) remembering that an interval is itself an estimate subject to error and generally provides only a rough indication of uncertainty given that all of the assumptions used to create it are correct and, thus, for example, does not "rule out" values outside the interval. Amrhein, Trafimow, and Greenland (2019) suggest that interval estimates be interpreted as "compatibility" intervals rather than as "confidence" intervals, showing the values that are most compatible with the data, under the model used to compute the interval. They argue that such an interpretation and the practices outlined here can help guard against overconfidence.

It is worth noting that Tong (2019) disagrees with using *p*-values as descriptive statistics. "Divorced from the probability

claims attached to such quantities (confidence levels, nominal Type I errors, and so on), there is no longer any reason to privilege such quantities over descriptive statistics that more directly characterize the data at hand." He further states, "Methods with alleged generality, such as the *p*-value or Bayes factor, should be avoided in favor of discipline- and problem-specific solutions that can be designed to be fit for purpose."

Failing to **be open** in reporting leads to publication bias. Ioannidis (2019) notes the high level of selection bias prevalent in biomedical journals. He defines "selection" as "the collection of choices that lead from the planning of a study to the reporting of *p*-values." As an illustration of one form of selection bias, Ioannidis compared "the set of *p*-values reported in the full text of an article with the set of *p*-values reported in the abstract." The main finding, he says, "was that *p*-values chosen for the abstract tended to show greater significance than those reported in the text, and that the gradient was more pronounced in some types of journals and types of designs." Ioannidis notes, however, that selection bias "can be present regardless of the approach to inference used." He argues that in the long run, "the only direct protection must come from standards for reproducible research."

To **be open**, remember that one study is rarely enough. The words "a groundbreaking new study" might be loved by news writers but must be resisted by researchers. Breaking ground is only the first step in building a house. It will be suitable for habitation only after much more hard work.

**Be open** by providing sufficient information so that other researchers can execute meaningful alternative analyses. van Dongen et al. (2019) provide an illustrative example of such alternative analyses by different groups attacking the same problem.

Being open goes hand in hand with being modest.

#### 3.4. Be Modest

Researchers of any ilk may rarely advertise their personal modesty. Yet the most successful ones cultivate a practice of **being modest** throughout their research, by understanding and clearly expressing the limitations of their work.

Being modest requires a reality check (Amrhein, Trafimow, and Greenland 2019). "A core problem," they observe, "is that both scientists and the public confound statistics with reality. But statistical inference is a thought experiment, describing the predictive performance of models about reality. Of necessity, these models are extremely simplified relative to the complexities of actual study conduct and of the reality being studied. Statistical results must eventually mislead us when they are used and communicated as if they present this complex reality, rather than a model for it. This is not a problem of our statistical methods. It is a problem of interpretation and communication of results."

**Be modest** in recognizing there is not a "true statistical model" underlying every problem, which is why it is wise to **thoughtfully** consider many possible models (Lavine 2019). Rougier (2019) calls on researchers to "recognize that behind every choice of null distribution and test statistic, there lurks

a plausible family of alternative hypotheses, which can provide more insight into the null distribution."

p-values, confidence intervals, and other statistical measures are all uncertain. Treating them otherwise is immodest overconfidence.

Remember that statistical tools have their limitations. Rose and McGuire (2019) show how use of stepwise regression in health care settings can lead to policies that are unfair.

Remember also that the amount of evidence for or against a hypothesis provided by p-values near the ubiquitous p < 0.05threshold (Johnson 2019) is usually much less than you think (Benjamin and Berger 2019; Colquhoun 2019; Greenland 2019).

Be modest about the role of statistical inference in scientific inference. "Scientific inference is a far broader concept than statistical inference," says Hubbard, Haig, and Parsa (2019). "A major focus of scientific inference can be viewed as the pursuit of significant sameness, meaning replicable and empirically generalizable results among phenomena. Regrettably, the obsession with users of statistical inference to report significant differences in data sets actively thwarts cumulative knowledge development."

The nexus of openness and modesty is to report everything while at the same time not concluding anything from a single study with unwarranted certainty. Because of the strong desire to inform and be informed, there is a relentless demand to state results with certainty. Again, accept uncertainty and embrace variation in associations and effects, because they are always there, like it or not. Understand that expressions of uncertainty are themselves uncertain. Accept that one study is rarely definitive, so encourage, sponsor, conduct, and publish replication studies. Then, use meta-analysis, evidence reviews, and Bayesian methods to synthesize evidence across studies.

Resist the urge to overreach in the generalizability of claims, Watch out for pressure to embellish the abstract or the press release. If the study's limitations are expressed in the paper but not in the abstract, they may never be read.

Be modest by encouraging others to reproduce your work. Of course, for it to be reproduced readily, you will necessarily have been **thoughtful** in conducting the research and **open** in presenting it.

Hubbard and Carriquiry (see their "do list" in Section 7) suggest encouraging reproduction of research by giving "a byline status for researchers who reproduce studies." They would like to see digital versions of papers dynamically updated to display "Reproduced by..." below original research authors' names or "not yet reproduced" until it is reproduced.

Indeed, when it comes to reproducibility, Amrhein, Trafimow, and Greenland (2019) demand that we be modest in our expectations. "An important role for statistics in research is the summary and accumulation of information," they say. "If replications do not find the same results, this is not necessarily a crisis, but is part of a natural process by which science evolves. The goal of scientific methodology should be to direct this evolution toward ever more accurate descriptions of the world and how it works, not toward ever more publication of inferences, conclusions, or decisions."

Referring to replication studies in psychology, McShane et al. (2019) recommend that future large-scale replication projects "should follow the 'one phenomenon, many studies' approach of the Many Labs project and Registered Replication Reports rather than the 'many phenomena, one study' approach of the Open Science Collaboration project. In doing so, they should systematically vary method factors across the laboratories involved in the project." This approach helps achieve the goals of Amrhein, Trafimow, and Greenland (2019) by increasing understanding of why and when results replicate or fail to do so, yielding more accurate descriptions of the world and how it works. It also speaks to significant sameness versus significant difference a la Hubbard, Haig, and Parsa (2019).

Kennedy-Shaffer's (2019) historical perspective on statistical significance reminds us to be modest, by prompting us to recall how the current state of affairs in *p*-values has come to be.

Finally, **be modest** by recognizing that different readers may have very different stakes on the results of your analysis, which means you should try to take the role of a neutral judge rather than an advocate for any hypothesis. This can be done, for example, by pairing every null p-value with a p-value testing an equally reasonable alternative, and by discussing the endpoints of every interval estimate (not only whether it contains the null).

Accept that both scientific inference and statistical inference are hard, and understand that no knowledge will be efficiently advanced using simplistic, mechanical rules and procedures. Accept also that pure objectivity is an unattainable goal—no matter how laudable-and that both subjectivity and expert judgment are intrinsic to the conduct of science and statistics. Accept that there will always be uncertainty, and be thoughtful, open, and modest. ATOM.

And to push this acronym further, we argue in the next section that institutional change is needed, so we put forward that change is needed at the ATOMIC level. Let's go.

#### 4. Editorial, Educational and Other Institutional **Practices Will Have to Change**

Institutional reform is necessary for moving beyond statistical significance in any context—whether journals, education, academic incentive systems, or others. Several papers in this special issue focus on reform.

Goodman (2019) notes considerable social change is needed in academic institutions, in journals, and among funding and regulatory agencies. He suggests (see Section 7) partnering "with science reform movements and reformers within disciplines, journals, funding agencies and regulators to promote and reward 'reproducible' science and diminish the impact of statistical significance on publication, funding and promotion." Similarly, Colquhoun (2019) says, "In the end, the only way to solve the problem of reproducibility is to do more replication and to reduce the incentives that are imposed on scientists to produce unreliable work. The publish-or-perish culture has damaged science, as has the judgment of their work by silly metrics."

Trafimow (2019), who added energy to the discussion of pvalues a few years ago by banning them from the journal he edits (Fricker et al. 2019), suggests five "nonobvious changes" to editorial practice. These suggestions, which demand reevaluating traditional practices in editorial policy, will not be trivial to implement but would result in massive change in some journals. Locascio (2017, 2019) suggests that evaluation of manuscripts for publication should be "results-blind." That is, manuscripts should be assessed for suitability for publication based on the substantive importance of the research without regard to their reported results. Kmetz (2019) supports this approach as well and says that it would be a huge benefit for reviewers, "freeing [them] from their often thankless present jobs and instead allowing them to review research designs for their potential to provide useful knowledge." (See also "registered reports" from the Center for Open Science (https://cos.io/rr/?\_ga=2.184185454.979594832.1547755516-1193527346.1457026171) and "registered replication reports" from the Association for Psychological Science (https://www.psychologicalscience.org/publications/replication) in relation to this concept.)

Amrhein, Trafimow, and Greenland (2019) ask if results-blind publishing means that anything goes, and then answer affirmatively: "Everything should be published in some form if whatever we measured made sense before we obtained the data because it was connected in a potentially useful way to some research question." Journal editors, they say, "should be proud about [their] exhaustive methods sections" and base their decisions about the suitability of a study for publication "on the quality of its materials and methods rather than on results and conclusions; the quality of the presentation of the latter is only judged after it is determined that the study is valuable based on its materials and methods."

A "variation on this theme is *pre-registered replication*, where a *replication* study, rather than the original study, is subject to strict pre-registration (e.g., Gelman 2015)," says Tong (2019). "A broader vision of this idea (Mogil and Macleod 2017) is to carry out a whole series of exploratory experiments *without* any formal statistical inference, and summarize the results by descriptive statistics (including graphics) or even just disclosure of the raw data. When results from this series of experiments converge to a single working hypothesis, it can *then* be subjected to a pre-registered, randomized and blinded, appropriately powered confirmatory experiment, carried out by another laboratory, in which valid statistical inference may be made."

Hurlbert, Levine, and Utts (2019) urge abandoning the use of "statistically significant" in all its forms and encourage journals to provide instructions to authors along these lines: "There is now wide agreement among many statisticians who have studied the issue that for reporting of statistical tests yielding *p*-values it is illogical and inappropriate to dichotomize the *p*-scale and describe results as 'significant' and 'nonsignificant.' Authors are strongly discouraged from continuing this never justified practice that originated from confusions in the early history of modern statistics."

Hurlbert, Levine, and Utts (2019) also urge that the ASA Statement on P-Values and Statistical Significance "be sent to the editor-in-chief of every journal in the natural, behavioral and social sciences for forwarding to their respective editorial boards and stables of manuscript reviewers. That would be a good way to quickly improve statistical understanding and practice." Kmetz (2019) suggests referring to the ASA statement whenever submitting a paper or revision to any editor, peer reviewer, or prospective reader. Hurlbert et al. encourage a "community grassroots effort" to encourage change in journal procedures.

Campbell and Gustafson (2019) propose a statistical model for evaluating publication policies in terms of weighing novelty of studies (and the likelihood of those studies subsequently being found false) against pre-specified study power. They observe that "no publication policy will be perfect. Science is inherently challenging and we must always be willing to accept that a certain proportion of research is potentially false."

Statistics education will require major changes at all levels to move to a post "p < 0.05" world. Two papers in this special issue make a specific start in that direction (Maurer et al. 2019; Steel, Liermann, and Guttorp 2019), but we hope that volumes will be written on this topic in other venues. We are excited that, with support from the ASA, the US Conference on Teaching Statistics (USCOTS) will focus its 2019 meeting on teaching inference.

The change that needs to happen demands change to editorial practice, to the teaching of statistics at every level where inference is taught, and to much more. However...

### 5. It is Going to Take Work, and it is Going to Take Time

If it were easy, it would have already been done, because as we have noted, this is nowhere near the first time the alarm has been sounded.

Why is eliminating the use of *p*-values as a truth arbiter so hard? "The basic explanation is neither philosophical nor scientific, but sociologic; everyone uses them," says Goodman (2019). "It's the same reason we can use money. When everyone believes in something's value, we can use it for real things; money for food, and *p*-values for knowledge claims, publication, funding, and promotion. It doesn't matter if the *p*-value doesn't mean what people think it means; it becomes valuable because of what it buys."

Goodman observes that statisticians alone cannot address the problem, and that "any approach involving only statisticians will not succeed." He calls on statisticians to ally themselves "both with scientists in other fields and with broader based, multidisciplinary scientific reform movements. What statisticians can do within our own discipline is important, but to effectively disseminate or implement virtually any method or policy, we need partners."

"The loci of influence," Goodman says, "include journals, scientific lay and professional media (including social media), research funders, healthcare payors, technology assessors, regulators, academic institutions, the private sector, and professional societies. They also can include policy or informational entities like the National Academies...as well as various other science advisory bodies across the government. Increasingly, they are also including non-traditional science reform organizations comprised both of scientists and of the science literate lay public...and a broad base of health or science advocacy groups..."

It is no wonder, then, that the problem has persisted for so long. And persist it has! Hubbard (2019) looked at citation-count data on twenty-five articles and books severely critical of the effect of null hypothesis significance testing (NHST) on good science. Though issues were well known, Hubbard says, this did nothing to stem NHST usage over time.

Greenland (personal communication, January 25, 2019) notes that cognitive biases and perverse incentives to offer firm conclusions where none are warranted can warp the use of any method. "The core human and systemic problems are not addressed by shifting blame to *p*-values and pushing alternatives as magic cures—especially alternatives that have been subject to little or no comparative evaluation in either classrooms or practice," Greenland said. "What we need now is to move beyond debating only our methods and their interpretations, to concrete proposals for elimination of systemic problems such as pressure to produce noteworthy findings rather than to produce reliable studies and analyses. Review and provisional acceptance of reports before their results are given to the journal (Locascio 2019) is one way to address that pressure, but more ideas are needed since review of promotions and funding applications cannot be so blinded. The challenges of how to deal with human biases and incentives may be the most difficult we must face." Supporting this view is McShane and Gal's (2016, 2017) empirical demonstration of cognitive dichotomization errors among biomedical and social science researchers—and even among statisticians.

Challenges for editors and reviewers are many. Here's an example: Fricker et al. (2019) observed that when p-values were suspended from the journal Basic and Applied Social Psychology authors tended to overstate conclusions.

With all the challenges, how do we get from here to there, from a "p < 0.05" world to a post "p < 0.05" world?

Matthews (2019) notes that "Any proposal encouraging changes in inferential practice must accept the ubiquity of NHST....Pragmatism suggests, therefore, that the best hope of achieving a change in practice lies in offering inferential tools that can be used alongside the concepts of NHST, adding value to them while mitigating their most egregious features."

Benjamin and Berger (2019) propose three practices to help researchers during the transition away from use of statistical significance. "...[O]ur goal is to suggest minimal changes that would require little effort for the scientific community to implement," they say. "Motivating this goal are our hope that easy (but impactful) changes might be adopted and our worry that more complicated changes could be resisted simply because they are perceived to be too difficult for routine implementation."

Yet there is also concern that progress will stop after a small step or two. Even some proponents of small steps are clear that those small steps still carry us far short of the destination.

For example, Matthews (2019) says that his proposed methodology "is not a panacea for the inferential ills of the research community." But that doesn't make it useless. It may "encourage researchers to move beyond NHST and explore the statistical armamentarium now available to answer the central question of research: what does our study tell us?" he says. It "provides a bridge between the dominant but flawed NHST paradigm and the less familiar but more informative methods of Bayesian estimation."

Likewise, Benjamin and Berger (2019) observe, "In research communities that are deeply attached to reliance on 'p < 0.05,' our recommendations will serve as initial steps away from this attachment. We emphasize that our recommendations are intended merely as initial, temporary steps and that many further steps will need to be taken to reach the ultimate destination: a holistic interpretation of statistical evidence that fully conforms to the principles laid out in the ASA Statement..."

Yet, like the authors of this editorial, not all authors in this special issue support gradual approaches with transitional methods.

Some (e.g., Amrhein, Trafimow, and Greenland 2019; Hurlbert, Levine, and Utts 2019; McShane et al. 2019) prefer to rip off the bandage and abandon use of statistical significance altogether. In short, no more dichotomizing p-values into categories of "significance." Notably, these authors do not suggest banning the use of p-values, but rather suggest using them descriptively, treating them as continuous, and assessing their weight or import with nuanced thinking, clear language, and full understanding of their properties.

So even when there is agreement on the destination, there is disagreement about what road to take. The questions around reform need consideration and debate. It might turn out that different fields take different roads.

The catalyst for change may well come from those people who fund, use, or depend on scientific research, say Calin-Jageman and Cumming (2019). They believe this change has not yet happened to the desired level because of "the cognitive opacity of the NHST approach: the counter-intuitive p-value (it's good when it is small), the mysterious null hypothesis (you want it to be false), and the eminently confusable Type I and Type II errors."

Reviewers of this editorial asked, as some readers of it will, is a p-value threshold ever okay to use? We asked some of the authors of articles in the special issue that question as well. Authors identified four general instances. Some allowed that, while p-value thresholds should not be used for inference, they might still be useful for applications such as industrial quality control, in which a highly automated decision rule is needed and the costs of erroneous decisions can be carefully weighed when specifying the threshold. Other authors suggested that such dichotomized use of p-values was acceptable in modelfitting and variable selection strategies, again as automated tools, this time for sorting through large numbers of potential models or variables. Still others pointed out that *p*-values with very low thresholds are used in fields such as physics, genomics, and imaging as a filter for massive numbers of tests. The fourth instance can be described as "confirmatory setting[s] where the study design and statistical analysis plan are specified prior to data collection, and then adhered to during and after it" (Tong 2019). Tong argues these are the only proper settings for formal statistical inference. And Wellek (2017) says at present it is essential in these settings. "[B]inary decision making is indispensable in medicine and related fields," he says. "[A] radical rejection of the classical principles of statistical inference...is of virtually no help as long as no conclusively substantiated alternative can be offered."

Eliminating the declaration of "statistical significance" based on p < 0.05 or other arbitrary thresholds will be easier in some venues than others. Most journals, if they are willing, could fairly rapidly implement editorial policies to effect these changes. Suggestions for how to do that are in this special issue of The American Statistician. However, regulatory agencies might require longer timelines for making changes. The U.S. Food and

Drug Administration (FDA), for example, has long established drug review procedures that involve comparing *p*-values to significance thresholds for Phase III drug trials. Many factors demand consideration, not the least of which is how to avoid turning every drug decision into a court battle. Goodman (2019) cautions that, even as we seek change, "we must respect the reason why the statistical procedures are there in the first place." Perhaps the ASA could convene a panel of experts, internal and external to FDA, to provide a workable new paradigm. (See Ruberg et al. 2019, who argue for a Bayesian approach that employs data from other trials as a "prior" for Phase 3 trials.)

Change is needed. Change has been needed for decades. Change has been called for by others for quite a while. So...

#### 6. Why Will Change Finally Happen Now?

In 1991, a confluence of weather events created a monster storm that came to be known as "the perfect storm," entering popular culture through a book (Junger 1997) and a 2000 movie starring George Clooney. Concerns about reproducible science, falling public confidence in science, and the initial impact of the ASA statement in heightening awareness of long-known problems created a perfect storm, in this case, a good storm of motivation to make lasting change. Indeed, such change was the intent of the ASA statement, and we expect this special issue of TAS will inject enough additional energy to the storm to make its impact widely felt.

We are not alone in this view. "60+ years of incisive criticism has not yet dethroned NHST as the dominant approach to inference in many fields of science," note Calin-Jageman and Cumming (2019). "Momentum, though, seems to finally be on the side of reform."

Goodman (2019) agrees: "The initial slow speed of progress should not be discouraging; that is how all broad-based social movements move forward and we should be playing the long game. But the ball is rolling downhill, the current generation is inspired and impatient to carry this forward."

So, let's do it. Let's move beyond "statistically significant," even if upheaval and disruption are inevitable for the time being. It's worth it. In a world beyond "p < 0.05," by breaking free from the bonds of statistical significance, statistics in science and policy will become more significant than ever.

#### 7. Authors' Suggestions

The editors of this special TAS issue on statistical inference asked all the contact authors to help us summarize the guidance they provided in their papers by providing us a short list of do's. We asked them to be specific but concise and to be active—start each with a verb. Here is the complete list of the authors' responses, ordered as the papers appear in this special issue.

#### 7.1. Getting to a Post "p < 0.05" Era

## Ioannidis, J., What Have We (Not) Learnt From Millions of Scientific Papers With p-Values?

1. Do not use *p*-values, unless you have clearly thought about the need to use them and they still seem the best choice.

- 2. Do not favor "statistically significant" results.
- 3. Do be highly skeptical about "statistically significant" results at the 0.05 level.

## Goodman, S., Why Is Getting Rid of p-Values So Hard? Musings on Science and Statistics

- Partner with science reform movements and reformers within disciplines, journals, funding agencies and regulators to promote and reward reproducible science and diminish the impact of statistical significance on publication, funding and promotion.
- 2. Speak to and write for the multifarious array of scientific disciplines, showing how statistical uncertainty and reasoning can be conveyed in non-"bright-line" ways both with conventional and alternative approaches. This should be done not just in didactic articles, but also in original or reanalyzed research, to demonstrate that it is publishable.
- 3. Promote, teach and conduct meta-research within many individual scientific disciplines to demonstrate the adverse effects in each of over-reliance on and misinterpretation of *p*-values and significance verdicts in individual studies and the benefits of emphasizing estimation and cumulative evidence.
- 4. Require reporting a quantitative measure of certainty—a "confidence index"—that an observed relationship, or claim, is true. Change analysis goal from achieving significance to appropriately estimating this confidence.
- 5. Develop and share teaching materials, software, and published case examples to help with all of the do's above, and to spread progress in one discipline to others.

## Hubbard, R., Will the ASA's Efforts to Improve Statistical Practice be Successful? Some Evidence to the Contrary

This list applies to the ASA and to the professional statistics community more generally.

- 1. Specify, where/if possible, those situations in which the *p*-value plays a clearly valuable role in data analysis and interpretation.
- 2. Contemplate issuing a statement abandoning the use of *p*-values in null hypothesis significance testing.

#### Kmetz, J., Correcting Corrupt Research: Recommendations for the Profession to Stop Misuse of p-Values

- 1. Refer to the ASA statement on *p*-values whenever submitting a paper or revision to any editor, peer reviewer, or prospective reader. Many in the field do not know of this statement, and having the support of a prestigious organization when authoring any research document will help stop corrupt research from becoming even more dominant than it is.
- 2. Train graduate students and future researchers by having them reanalyze published studies and post their findings to appropriate websites or weblogs. This practice will benefit not only the students, but will benefit the professions, by increasing the amount of replicated (or nonreplicated) research available and readily accessible, and as well as reformer organizations that support replication.
- 3. Join one or more of the reformer organizations formed or forming in many research fields, and support and publicize their efforts to improve the quality of research practices.

- 4. Challenge editors and reviewers when they assert that incorrect practices and interpretations of research, consistent with existing null hypothesis significance testing and beliefs regarding p-values, should be followed in papers submitted to their journals. Point out that new submissions have been prepared to be consistent with the ASA statement on pvalues.
- 5. Promote emphasis on research quality rather than research quantity in universities and other institutions where professional advancement depends heavily on research "productivity," by following the practices recommended in this special journal edition. This recommendation will fall most heavily on those who have already achieved success in their fields, perhaps by following an approach quite different from that which led to their success; whatever the merits of that approach may have been, one objectionable outcome of it has been the production of voluminous corrupt research and creation of an environment that promotes and protects it. We must do better.

#### Hubbard, D., and Carriquiry, A., Quality Control for Scientific Research: Addressing Reproducibility, Responsiveness and Relevance

- 1. Compute and prominently display the probability the hypothesis is true (or a probability distribution of an effect size) or provide sufficient information for future researchers and policy makers to compute it.
- 2. Promote publicly displayed quality control metrics within your field—in particular, support tracking of reproduction studies and computing the "level 1" and even "level 2" priors as required for #1 above.
- 3. Promote a byline status for researchers who reproduce studies: Digital versions are dynamically updated to display "Reproduced by...." below original research authors' names or "Not yet reproduced" until it is reproduced.

#### Brownstein, N., Louis, T., O'Hagan, A., and Pendergast, J., The Role of Expert Judgment in Statistical Inference and Evidence-**Based Decision-Making**

- 1. Staff the study team with members who have the necessary knowledge, skills and experience—statistically, scientifically, and otherwise.
- 2. Include key members of the research team, including statisticians, in all scientific and administrative meetings.
- 3. Understand that subjective judgments are needed in all stages of a study.
- 4. Make all judgments as carefully and rigorously as possible and document each decision and rationale for transparency and reproducibility.
- 5. Use protocol-guided elicitation of judgments.
- 6. Statisticians specifically should:
  - Refine oral and written communication skills.
  - Understand their multiple roles and obligations as collab-
  - Take an active leadership role as a member of the scientific team; contribute throughout all phases of the study.

- Co-own the subject matter—understand a sufficient amount about the relevant science/policy to meld statistical and subject-area expertise.
- Promote the expectation that your collaborators co-own statistical issues.
- Write a statistical analysis plan for all analyses and track any changes to that plan over time.
- Promote co-responsibility for data quality, security, and documentation.
- · Reduce unplanned and uncontrolled modeling/testing (HARK-ing, *p*-hacking); document all analyses.

#### O'Hagan, A., Expert Knowledge Elicitation: Subjective but Scientific

- 1. Elicit expert knowledge when data relating to a parameter of interest is weak, ambiguous or indirect.
- 2. Use a well-designed protocol, such as SHELF, to ensure expert knowledge is elicited in as scientific and unbiased a way as possible.

#### Kennedy-Shaffer, L., Before p < 0.05 to Beyond p < 0.05: Using History to Contextualize p-Values and Significance Testing

- 1. Ensure that inference methods match intuitive understandings of statistical reasoning.
- 2. Reduce the computational burden for nonstatisticians using statistical methods.
- 3. Consider changing conditions of statistical and scientific inference in developing statistical methods.
- 4. Address uncertainty quantitatively and in ways that reward increased precision.

#### Hubbard, R., Haig, B. D., and Parsa, R. A., The Limited Role of Formal Statistical Inference in Scientific Inference

- 1. Teach readers that although deemed equivalent in the social, management, and biomedical sciences, formal methods of statistical inference and scientific inference are very different animals.
- 2. Show these readers that formal methods of statistical inference play only a restricted role in scientific inference.
- 3. Instruct researchers to pursue significant sameness (i.e., replicable and empirically generalizable results) rather than significant differences in results.
- 4. Demonstrate how the pursuit of significant differences actively impedes cumulative knowledge development.

#### McShane, B., Tackett, J., Böckenholt, U., and Gelman, A., Large Scale Replication Projects in Contemporary Psychological Research

- 1. When planning a replication study of a given psychological phenomenon, bear in mind that replication is complicated in psychological research because studies can never be direct or exact replications of one another, and thus heterogeneityeffect sizes that vary from one study of the phenomenon to the next—cannot be avoided.
- 2. Future large scale replication projects should follow the "one phenomenon, many studies" approach of the Many Labs project and Registered Replication Reports rather than the

- "many phenomena, one study" approach of the Open Science Collaboration project. In doing so, they should systematically vary method factors across the laboratories involved in the project.
- 3. Researchers analyzing the data resulting from large scale replication projects should do so via a hierarchical (or multilevel) model fit to the totality of the individual-level observations. In doing so, all theoretical moderators should be modeled via covariates while all other potential moderators—that is, method factors—should induce variation (i.e., heterogeneity).
- 4. Assessments of replicability should not depend solely on estimates of effects, or worse, significance tests based on them. Heterogeneity must also be an important consideration in assessing replicability.

#### 7.2. Interpreting and Using p

#### Greenland, S., Valid p-Values Behave Exactly as They Should: Some Misleading Criticisms of p-Values and Their Resolution With s-Values

- 1. Replace any statements about statistical significance of a result with the p-value from the test, and present the p-value as an equality, not an inequality. For example, if p=0.03 then "...was statistically significant" would be replaced by "...had p=0.03," and "p<0.05" would be replaced by "p=0.03." (An exception: If p is so small that the accuracy becomes very poor then an inequality reflecting that limit is appropriate; e.g., depending on the sample size, p-values from normal or  $\chi^2$  approximations to discrete data often lack even 1-digit accuracy when p<0.0001.) In parallel, if p=0.25 then "...was not statistically significant" would be replaced by "...had p=0.25," and "p>0.05" would be replaced by "p=0.25."
- 2. Present *p*-values for more than one possibility when testing a targeted parameter. For example, if you discuss the *p*-value from a test of a null hypothesis, also discuss alongside this null *p*-value another *p*-value for a plausible alternative parameter possibility (ideally the one used to calculate power in the study proposal). As another example: if you do an equivalence test, present the *p*-values for both the lower and upper bounds of the equivalence interval (which are used for equivalence tests based on two one-sided tests).
- 3. Show confidence intervals for targeted study parameters, but also supplement them with p-values for testing relevant hypotheses (e.g., the p-values for both the null and the alternative hypotheses used for the study design or proposal, as in #2). Confidence intervals only show clearly what is in or out of the interval (i.e., a 95% interval only shows clearly what has p > 0.05 or  $p \le 0.05$ ), but more detail is often desirable for key hypotheses under contention.
- 4. Compare groups and studies directly by showing p-values and interval estimates for their differences, not by comparing p-values or interval estimates from the two groups or studies. For example, seeing p=0.03 in males and p=0.12 in females does **not** mean that different associations were seen in males and females; instead, one needs a p-value and confidence interval for the difference in the sex-specific

- associations to examine the between-sex difference. Similarly, if an early study reported a confidence interval which excluded the null and then a subsequent study reported a confidence interval which included the null, that does not mean the studies gave conflicting results or that the second study failed to replicate the first study; instead, one needs a *p*-value and confidence interval for the difference in the study-specific associations to examine the between-study difference. In all cases, differences-between-differences must be analyzed directly by statistics for that purpose.
- 5. Supplement a focal p-value p with its Shannon information transform (s-value or surprisal)  $s = -\log_2(p)$ . This measures the amount of information supplied by the test against the tested hypothesis (or model): Rounded off, the s-value s shows the number of heads in a row one would need to see when tossing a coin to get the same amount of information against the tosses being "fair" (independent with "heads" probability of 1/2) instead of being loaded for heads. For example, if p = 0.03, this represents  $-\log_2(0.03) = 5$  bits of information against the hypothesis (like getting 5 heads in a trial of "fairness" with 5 coin tosses); and if p = 0.25, this represents only  $-\log_2(0.25) = 2$  bits of information against the hypothesis (like getting 2 heads in a trial of "fairness" with only 2 coin tosses).

#### Betensky, R., The p-Value Requires Context, Not a Threshold

- 1. Interpret the *p*-value in light of its context of sample size and meaningful effect size.
- 2. Incorporate the sample size and meaningful effect size into a decision to reject the null hypothesis.

## Anderson, A., Assessing Statistical Results: Magnitude, Precision and Model Uncertainty

- Evaluate the importance of statistical results based on their practical implications.
- 2. Evaluate the strength of empirical evidence based on the precision of the estimates and the plausibility of the modeling choices
- 3. Seek out subject matter expertise when evaluating the importance and the strength of empirical evidence.

#### Heck, P., and Krueger, J., Putting the p-Value in Its Place

- 1. Use the *p*-value as a heuristic, that is, as the base for a tentative inference regarding the presence or absence of evidence against the tested hypothesis.
- 2. Supplement the *p*-value with other, conceptually distinct methods and practices, such as effect size estimates, likelihood ratios, or graphical representations.
- 3. Strive to embed statistical hypothesis testing within strong *a priori* theory and a context of relevant prior empirical evidence.

#### Johnson, V., Evidence From Marginally Significant t-Statistics

- 1. Be transparent in the number of outcome variables that were analyzed.
- Report the number (and values) of all test statistics that were calculated.
- Provide access to protocols for studies involving human or animal subjects.

- 4. Clearly describe data values that were excluded from analysis and the justification for doing so.
- 5. Provide sufficient details on experimental design so that other researchers can replicate the experiment.
- 6. Describe only *p*-values less than 0.005 as being "statistically significant."

#### Fraser, D., The p-Value Function and Statistical Inference

- Determine a primary variable for assessing the hypothesis at issue.
- 2. Calculate its well defined distribution function, respecting continuity.
- 3. Substitute the observed data value to obtain the "*p*-value function."
- 4. Extract the available well defined confidence bounds, confidence intervals, and median estimate.
- 5. Know that you don't have an intellectual basis for decisions.

#### Rougier, J., p-Values, Bayes Factors, and Sufficiency

 Recognize that behind every choice of null distribution and test statistic, there lurks a plausible family of alternative hypotheses, which can provide more insight into the null distribution.

## Rose, S., and McGuire, T., Limitations of p-Values and R-Squared for Stepwise Regression Building: A Fairness Demonstration in Health Policy Risk Adjustment

- 1. Formulate a clear objective for variable inclusion in regression procedures.
- 2. Assess all relevant evaluation metrics.
- 3. Incorporate algorithmic fairness considerations.

#### 7.3. Supplementing or Replacing p

### Blume, J., Greevy, R., Welty, V., Smith, J., and DuPont, W., An Introduction to Second Generation p-Values

- Construct a composite null hypothesis by specifying the range of effects that are not scientifically meaningful (do this before looking at the data). Why: Eliminating the conflict between scientific significance and statistical significance has numerous statistical and scientific benefits.
- 2. Replace classical *p*-values with second-generation *p*-values (SGPV). Why: SGPVs accommodate composite null hypotheses and encourage the proper communication of findings.
- 3. Interpret the SGPV as a high-level summary of what the data say. Why: Science needs a simple indicator of when the data support only meaningful effects (SGPV = 0), when the data support only trivially null effects (SGPV = 1), or when the data are inconclusive (0 < SGPV < 1).
- 4. Report an interval estimate of effect size (confidence interval, support interval, or credible interval) and note its proximity to the composite null hypothesis. Why: This is a more detailed description of study findings.
- 5. Consider reporting false discovery rates with SGPVs of 0 or 1. Why: FDRs gauge the chance that an inference is incorrect under assumptions about the data generating process and prior knowledge.

#### Goodman, W., Spruill, S., and Komaroff, E., A Proposed Hybrid Effect Size Plus p-Value Criterion: Empirical Evidence Supporting Its Use

- 1. Determine how far the true parameter's value would have to be, in your research context, from exactly equaling the conventional, point null hypothesis to consider that the distance is meaningfully large or practically significant.
- 2. Combine the conventional *p*-value criterion with a minimum effect size criterion to generate a two-criteria inference-indicator signal, which provides heuristic, but nondefinitive evidence, for inferring the parameter's true location.
- 3. Document the intended criteria for your inference procedures, such as a *p*-value cut-point and a minimum practically significant effect size, prior to undertaking the procedure.
- 4. Ensure that you use the appropriate inference method for the data that are obtainable and for the inference that is intended.
- 5. Acknowledge that every study is fraught with limitations from unknowns regarding true data distributions and other conditions that one's method assumes.

## Benjamin, D., and Berger, J., Three Recommendations for Improving the Use of p-Values

- 1. Replace the 0.05 "statistical significance" threshold for claims of novel discoveries with a 0.005 threshold and refer to *p*-values between 0.05 and 0.005 as "suggestive."
- 2. Report the data-based odds of the alternative hypothesis to the null hypothesis. If the data-based odds cannot be calculated, then use the *p*-value to report an upper bound on the data-based odds: 1/(-*ep* ln *p*).
- 3. Report your prior odds and posterior odds (prior odds \* data-based odds) of the alternative hypothesis to the null hypothesis. If the data-based odds cannot be calculated, then use your prior odds and the *p*-value to report an upper bound on your posterior odds: (prior odds) \* (1/(-ep ln p)).

## Colquhoun, D., The False Positive Risk: A Proposal Concerning What to Do About p-Values

- 1. Continue to provide *p*-values and confidence intervals. Although widely misinterpreted, people know how to calculate them and they aren't entirely useless. Just don't ever use the terms "statistically significant" or "nonsignificant."
- 2. Provide in addition an indication of false positive risk (FPR). This is the probability that the claim of a real effect on the basis of the *p*-value is in fact false. The FPR (not the *p*-value) is the probability that your result occurred by chance. For example, the fact that, under plausible assumptions, observation of a *p*-value close to 0.05 corresponds to an FPR of at least 0.2–0.3 shows clearly the weakness of the conventional criterion for "statistical significance."
- 3. Alternatively, specify the prior probability of there being a real effect that one would need to be able to justify in order to achieve an FPR of, say, 0.05.

#### Notes:

There are many ways to calculate the FPR. One, based on a point null and simple alternative can be calculated with the web calculator at <a href="http://fpr-calc.ucl.ac.uk/">http://fpr-calc.ucl.ac.uk/</a>. However other approaches to the calculation of FPR, based on different

assumptions, give results that are similar (Table 1 in Colquhoun 2019).

To calculate FPR it is necessary to specify a prior probability and this is rarely known. My recommendation 2 is based on giving the FPR for a prior probability of 0.5. Any higher prior probability of there being a real effect is not justifiable in the absence of hard data. In this sense, the calculated FPR is the minimum that can be expected. More implausible hypotheses would make the problem worse. For example, if the prior probability of there being a real effect were only 0.1, then observation of p=0.05 would imply a disastrously high FPR = 0.76, and in order to achieve an FPR of 0.05, you'd need to observe p=0.00045. Others (especially Goodman) have advocated giving likelihood ratios (LRs) in place of p-values. The FPR for a prior of 0.5 is simply 1/(1+LR), so to give the FPR for a prior of 0.5 is simply a more-easily-comprehensible way of specifying the LR, and so should be acceptable to frequentists and Bayesians.

## Matthews, R., Moving Toward the Post p < 0.05 Era via the Analysis of Credibility

- 1. Report the outcome of studies as effect sizes summarized by confidence intervals (CIs) along with their point estimates.
- 2. Make full use of the point estimate and width and location of the CI relative to the null effect line when interpreting findings. The point estimate is generally the effect size best supported by the study, irrespective of its statistical significance/nonsignificance. Similarly, tight CIs located far from the null effect line generally represent more compelling evidence for a nonzero effect than wide CIs lying close to that line.
- 3. Use the analysis of credibility (AnCred) to assess quantitatively the credibility of inferences based on the CI. AnCred determines the level of prior evidence needed for a new finding to provide credible evidence for a nonzero effect.
- 4. Establish whether this required level of prior evidence is supported by current knowledge and insight. If it is, the new result provides credible evidence for a nonzero effect, irrespective of its statistical significance/nonsignificance.

## Gannon, M., Pereira, C., and Polpo, A., Blending Bayesian and Classical Tools to Define Optimal Sample-Size-Dependent Significance Levels

- 1. Retain the useful concept of statistical significance and the same operational procedures as currently used for hypothesis tests, whether frequentist (Neyman–Pearson *p*-value tests) or Bayesian (Bayes-factor tests).
- 2. Use tests with a sample-size-dependent significance level—ours is optimal in the sense of the generalized Neyman–Pearson lemma.
- 3. Use a testing scheme that allows tests of any kind of hypothesis, without restrictions on the dimensionalities of the parameter space or the hypothesis. Note that this should include "sharp" hypotheses, which correspond to subsets of lower dimensionality than the full parameter space.
- 4. Use hypothesis tests that are compatible with the likelihood principle (LP). They can be easier to interpret consistently than tests that are not LP-compliant.

5. Use numerical methods to handle hypothesis-testing problems with high-dimensional sample spaces or parameter spaces.

#### Pogrow, S., How Effect Size (Practical Significance) Misleads Clinical Practice: The Case for Switching to Practical Benefit to Assess Applied Research Findings

- 1. Switch from reliance on statistical or practical significance to the more stringent statistical criterion of practical benefit for (a) assessing whether applied research findings indicate that an intervention is effective and should be adopted and scaled—particularly in complex organizations such as schools and hospitals and (b) determining whether relationships are sufficiently strong and explanatory to be used as a basis for setting policy or practice recommendations. Practical benefit increases the likelihood that observed benefits will replicate in subsequent research and in clinical practice by avoiding the problems associated with relying on small effect sizes.
- 2. Reform statistics courses in applied disciplines to include the principles of practical benefit, and have students review influential applied research articles in the discipline to determine which findings demonstrate practical benefit.
- 3. Recognize the need to develop different inferential statistical criteria for assessing the importance of applied research findings as compared to assessing basic research findings.
- 4. Consider consistent, noticeable improvements across contexts using the quick prototyping methods of improvement science as a preferable methodology for identifying effective practices rather than on relying on RCT methods.
- 5. Require that applied research reveal the actual unadjusted means/medians of results for all groups and subgroups, and that review panels take such data into account—as opposed to only reporting relative differences between adjusted means/medians. This will help preliminarily identify whether there appear to be clear benefits for an intervention.

#### 7.4. Adopting More Holistic Approaches

## McShane, B., Gal, D., Gelman, A., Robert, C., and Tackett, J., Abandon Statistical Significance

- 1. Treat *p*-values (and other purely statistical measures like confidence intervals and Bayes factors) continuously rather than in a dichotomous or thresholded manner. In doing so, bear in mind that it seldom makes sense to calibrate evidence as a function of *p*-values or other purely statistical measures because they are, among other things, typically defined relative to the generally uninteresting and implausible null hypothesis of zero effect and zero systematic error.
- 2. Give consideration to related prior evidence, plausibility of mechanism, study design and data quality, real world costs and benefits, novelty of finding, and other factors that vary by research domain. Do this always—not just once some *p*-value or other statistical threshold has been attained—and do this without giving priority to *p*-values or other purely statistical measures.

- 3. Analyze and report all of the data and relevant results rather than focusing on single comparisons that attain some p-value or other statistical threshold.
- 4. Conduct a decision analysis: p-value and other statistical threshold-based rules implicitly express a particular tradeoff between Type I and Type II error, but in reality this tradeoff should depend on the costs, benefits, and probabilities of all outcomes.
- 5. Accept uncertainty and embrace variation in effects: we can learn much (indeed, more) about the world by forsaking the false promise of certainty offered by dichotomous declarations of truth or falsity—binary statements about there being "an effect" or "no effect"—based on some p-value or other statistical threshold being attained.
- 6. Obtain more precise individual-level measurements, use within-person or longitudinal designs more often, and give increased consideration to models that use informative priors, that feature varying treatment effects, and that are multilevel or meta-analytic in nature.

#### Tong, C., Statistical Inference Enables Bad Science; Statistical Thinking Enables Good Science

- 1. Prioritize effort for sound data production: the planning, design, and execution of the study.
- 2. Build scientific arguments with many sets of data and multiple lines of evidence.
- 3. Recognize the difference between exploratory and confirmatory objectives and use distinct statistical strategies for each.
- 4. Use flexible descriptive methodology, including disciplined data exploration, enlightened data display, and regularized, robust, and nonparametric models, for exploratory research.
- 5. Restrict statistical inferences to confirmatory analyses for which the study design and statistical analysis plan are prespecified prior to, and strictly adhered to during, data acquisition.

#### Amrhein, V., Trafimow, D., and Greenland, S., Inferential Statistics as Descriptive Statistics: There Is No Replication Crisis If We Don't Expect Replication

- 1. Do not dichotomize, but embrace variation.
  - Report and interpret inferential statistics like the pvalue in a continuous fashion; do not use the word "significant."
  - (b) Interpret interval estimates as "compatibility intervals," showing effect sizes most compatible with the data, under the model used to compute the interval; do not focus on whether such intervals include or exclude zero.
  - Treat inferential statistics as highly unstable local descriptions of relations between models and the obtained data.
    - Free your "negative results" by allowing them to be potentially positive. Most studies with large p-values or interval estimates that include the null should be considered "positive," in the sense that they usually leave open the possibility of important effects (e.g., the effect sizes within the interval estimates).

- Free your "positive results" by allowing them to be different. Most studies with small p-values or interval estimates that are not near the null should be considered provisional, because in replication studies the p-values could be large and the interval estimates could show very different effect sizes.
- (iii) There is no replication crisis if we don't expect replication. Honestly reported results must vary from replication to replication because of varying assumption violations and random variation; excessive agreement itself would suggest deeper problems such as failure to publish results in conflict with group expectations.

#### Calin-Jageman, R., and Cumming, G., The New Statistics for Better Science: Ask How Much, How Uncertain, and What Else Is Known

- 1. Ask quantitative questions and give quantitative answers.
- 2. Countenance uncertainty in all statistical conclusions, seeking ways to quantify, visualize, and interpret the potential for
- 3. Seek replication, and use quantitative methods to synthesize across data sets as a matter of course.
- 4. Use Open Science practices to enhance the trustworthiness of research results.
- 5. Avoid, wherever possible, any use of *p*-values or NHST.

#### Ziliak, S., How Large Are Your G-Values? Try Gosset's Guinnessometrics When a Little "p" Is Not Enough

- G-10 Consider the Purpose of the Inquiry, and Compare with Best Practice. Falsification of a null hypothesis is not the main purpose of the experiment or observational study. Making money or beer or medicine—ideally more and better than the competition and best practice—is. Estimating the importance of your coefficient relative to results reported by others, is. To repeat, as the 2016 ASA Statement makes clear, merely falsifying a null hypothesis with a qualitative yes/no, exists/does not exist, significant/not significant answer, is not itself significant science, and should be eschewed.
- G-9 Estimate the Stakes (Or Eat Them). Estimation of magnitudes of effects, and demonstrations of their substantive meaning, should be the center of most inquiries. Failure to specify the stakes of a hypothesis is the first step toward eating them (gulp).
- G-8 Study Correlated Data: ABBA, Take a Chance on Me. Most regression models assume "iid" error terms independently and identically distributed-yet most data in the social and life sciences are correlated by systematic, nonrandom effects-and are thus not independent. Gosset solved the problem of correlated soil plots with the "ABBA" layout, maximizing the correlation of paired differences between the As and Bs with a perfectly balanced chiasmic arrangement.
- G-7 Minimize "Real Error" with the 3 R's: Represent, Replicate, Reproduce. A test of significance on a single set of data is nearly valueless. Fisher's p, Student's t, and other tests should only be used when there is actual repetition of the experi-

- ment. "One and done" is scientism, not scientific. Random error is not equal to real error, and is usually smaller and less important than the sum of nonrandom errors. Measurement error, confounding, specification error, and bias of the auspices are frequently larger in all the testing sciences, agronomy to medicine. Guinnessometrics minimizes real error by repeating trials on stratified and balanced vet independent experimental units, controlling as much as possible for local fixed effects.
- G-6 Economize with "Less is More": Small Samples of Independent Experiments. Small sample analysis and distribution theory has an economic origin and foundation: changing inputs to the beer on the large scale (for Guinness, enormous global scale) is risky, with more than money at stake. But smaller samples, as Gosset showed in decades of barley and hops experimentation, does not mean "less than," and Big Data is in any case not the solution for many problems.
- G-5 Keep Your Eyes on the Size Matters/How Much? Question. There will be distractions but the expected loss and profit functions rule, or should. Are regression coefficients or differences between means large or small? Compared to what? How do you know?
- G-4 Visualize. Parameter uncertainty is not the same thing as model uncertainty. Does the result hit you between the eyes? Does the study show magnitudes of effects across the entire distribution? Advances in visualization software continue to outstrip advances in statistical modeling, making more visualization a no brainer.
- G-3 Consider Posteriors and Priors too ("It pays to go Bayes"). The sample on hand is rarely the only thing that is "known." Subject matter expertise is an important prior input to statistical design and affects analysis of "posterior" results. For example, Gosset at Guinness was wise to keep quality assurance metrics and bottom line profit at the center of his inquiry. How does prior information fit into the story and evidence? Advances in Bayesian computing software make it easier and easier to do a Bayesian analysis, merging prior and posterior information, values, and knowledge.
- G-2 Cooperate Up, Down, and Across (Networks and Value *Chains*). For example, where would brewers be today without the continued cooperation of farmers? Perhaps back on the farm and not at the brewery making beer. Statistical science is social, and cooperation helps. Guinness financed a large share of modern statistical theory, and not only by supporting Gosset and other brewers with academic sabbaticals (Ziliak and McCloskey 2008).
- G-1 Answer the Brewer's Original Question ("How should you set the odds?"). No bright-line rule of statistical significance can answer the brewer's question. As Gosset said way back in 1904, how you set the odds depends on "the importance of the issues at stake" (e.g., the expected benefit and cost) together with the cost of obtaining new material.

#### Billheimer, D., Predictive Inference and Scientific Reproducibility

- 1. Predict observable events or quantities that you care about.
- 2. Quantify the uncertainty of your predictions.

#### Manski, C., Treatment Choice With Trial Data: Statistical **Decision Theory Should Supplant Hypothesis Testing**

- 1. Statisticians should relearn statistical decision theory, which received considerable attention in the middle of the twentieth century but was largely forgotten by the century's end.
- 2. Statistical decision theory should supplant hypothesis testing when statisticians study treatment choice with trial data.
- 3. Statisticians should use statistical decision theory when analyzing decision making with sample data more generally.

#### Manski, C., and Tetenov, A., Trial Size for Near Optimal Choice between Surveillance and Aggressive Treatment: Reconsidering MSLT-II

- 1. Statisticians should relearn statistical decision theory, which received considerable attention in the middle of the twentieth century but was largely forgotten by the century's end.
- 2. Statistical decision theory should supplant hypothesis testing when statisticians study treatment choice with trial data.
- 3. Statisticians should use statistical decision theory when analyzing decision making with sample data more generally.

#### Lavine, M., Frequentist, Bayes, or Other?

- 1. Look for and present results from many models that fit the data well.
- 2. Evaluate models, not just procedures.

#### Ruberg, S., Harrell, F., Gamalo-Siebers, M., LaVange, L., Lee J., Price K., and Peck C., Inference and Decision-Making for 21st Century Drug Development and Approval

- 1. Apply Bayesian paradigm as a framework for improving statistical inference and regulatory decision making by using probability assertions about the magnitude of a treatment effect.
- 2. Incorporate prior data and available information formally into the analysis of the confirmatory trials.
- 3. Justify and pre-specify how priors are derived and perform sensitivity analysis for a better understanding of the impact of the choice of prior distribution.
- 4. Employ quantitative utility functions to reflect key considerations from all stakeholders for optimal decisions via a probability-based evaluation of the treatment effects.
- 5. Intensify training in Bayesian approaches, particularly for decision makers and clinical trialists (e.g., physician scientists in FDA, industry and academia).

#### van Dongen, N., Wagenmakers, E.J., van Doorn, J., Gronau, Q., van Ravenzwaaij, D., Hoekstra, R., Haucke, M., Lakens, D., Hennig, C., Morey, R., Homer, S., Gelman, A., and Sprenger, J., Multiple Perspectives on Inference for Two Simple Statistical **Scenarios**

- 1. Clarify your statistical goals explicitly and unambiguously.
- 2. Consider the question of interest and choose a statistical approach accordingly.
- 3. Acknowledge the uncertainty in your statistical conclusions.
- 4. Explore the robustness of your conclusions by executing several different analyses.
- 5. Provide enough background information such that other researchers can interpret your results and possibly execute meaningful alternative analyses.

### 7.5. Reforming Institutions: Changing Publication Policies and Statistical Education

Trafimow, D., Five Nonobvious Changes in Editorial Practice for Editors and Reviewers to Consider When Evaluating Submissions in a Post P < 0.05 Universe

- 1. Tolerate ambiguity.
- 2. Replace significance testing with a priori thinking.
- 3. Consider the nature of the contribution, on multiple levels.
- 4. Emphasize thinking and execution, not results.
- 5. Consider that the assumption of random and independent sampling might be wrong.

## Locascio, J., The Impact of Results Blind Science Publishing on Statistical Consultation and Collaboration

For journal reviewers

- 1. Provide an initial provisional decision regarding acceptance for publication of a journal manuscript based exclusively on the judged importance of the research issues addressed by the study and the soundness of the reported methodology. (The latter would include appropriateness of data analysis methods.) Give no weight to the reported results of the study per se in the decision as to whether to publish or not.
- 2. To ensure #1 above is accomplished, commit to an initial decision regarding publication after having been provided with only the Introduction and Methods sections of a manuscript by the editor, not having seen the Abstract, Results, or Discussion. (The latter would be reviewed only if and after a generally irrevocable decision to publish has already been made.)

#### For investigators/manuscript authors

- 1. Obtain consultation and collaboration from statistical consultant(s) and research methodologist(s) early in the development and conduct of a research study.
- Emphasize the clinical and scientific importance of a study in the Introduction section of a manuscript, and give a clear, explicit statement of the research questions being addressed and any hypotheses to be tested.
- 3. Include a detailed statistical analysis subsection in the Methods section, which would contain, among other things, a justification of the adequacy of the sample size and the reasons various statistical methods were employed. For example, if null hypothesis significance testing and *p*-values are used, presumably supplemental to other methods, justify why those methods apply and will provide useful additional information in this particular study.
- 4. Submit for publication reports of well-conducted studies on important research issues regardless of findings, for example, even if only null effects were obtained, hypotheses were not confirmed, mere replication of previous results were found, or results were inconsistent with established theories.

#### Hurlbert, S., Levine, R., and Utts, J., Coup de Grâce for a Tough Old Bull: "Statistically Significant" Expires

1. Encourage journal editorial boards to disallow use of the phrase "statistically significant," or even "significant," in manuscripts they will accept for review.

- 2. Give primary emphasis in abstracts to the magnitudes of those effects most conclusively demonstrated and of greatest import to the subject matter.
- 3. Report precise *p*-values or other indices of evidence against null hypotheses as continuous variables not requiring any labeling.
- 4. Understand the meaning of and rationale for neoFisherian significance assessment (NFSA).

#### Campbell, H., and Gustafson, P., The World of Research Has Gone Berserk: Modeling the Consequences of Requiring "Greater Statistical Stringency" for Scientific Publication

1. Consider the meta-research implications of implementing new publication/funding policies. Journal editors and research funders should attempt to model the impact of proposed policy changes before any implementation. In this way, we can anticipate the policy impacts (both positive and negative) on the types of studies researchers pursue and the types of scientific articles that ultimately end up published in the literature.

## Fricker, R., Burke, K., Han, X., and Woodall, W., Assessing the Statistical Analyses Used in Basic and Applied Social Psychology After Their p-Value Ban

- 1. Use measures of statistical significance combined with measures of practical significance, such as confidence intervals on effect sizes, in assessing research results.
- 2. Classify research results as either exploratory or confirmatory and appropriately describe them as such in all published documentation.
- 3. Define precisely the population of interest in research studies and carefully assess whether the data being analyzed are representative of the population.
- 4. Understand the limitations of inferential methods applied to observational, convenience, or other nonprobabilistically sampled data.

## Maurer, K., Hudiburgh, L., Werwinski, L., and Bailer J., Content Audit for p-Value Principles in Introductory Statistics

- 1. Evaluate the coverage of *p*-value principles in the introductory statistics course using rubrics or other systematic assessment guidelines.
- 2. Discuss and deploy improvements to curriculum coverage of *p*-value principles.
- Meet with representatives from other departments, who have majors taking your statistics courses, to make sure that inference is being taught in a way that fits the needs of their disciplines.
- 4. Ensure that the correct interpretation of *p*-value principles is a point of emphasis for all faculty members and embedded within all courses of instruction.

## Steel, A., Liermann, M., and Guttorp, P., Beyond Calculations: A Course in Statistical Thinking

- 1. Design curricula to teach students how statistical analyses are embedded within a larger science life-cycle, including steps such as project formulation, exploratory graphing, peer review, and communication beyond scientists.
- 2. Teach the *p*-value as only one aspect of a complete data analysis.

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- 3. Prioritize helping students build a strong understanding of what testing and estimation can tell you over teaching statistical procedures.
- 4. Explicitly teach statistical communication. Effective communication requires that students clearly formulate the benefits and limitations of statistical results.
- 5. Force students to struggle with poorly defined questions and real, messy data in statistics classes.
  - 5. Encourage students to match the mathematical metric (or data summary) to the scientific question. Teaching students to create customized statistical tests for custom metrics allows statistics to move beyond the mean and pinpoint specific scientific questions.

#### **Acknowledgments**

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> Gratefully, Ronald L. Wasserstein American Statistical Association, Alexandria, VA ron@amstat.org

Allen L. Schirm Mathematica Policy Research (retired), Washington, DC allenschirm@gmail.com

Nicole A. Lazar

Department of Statistics, University of Georgia, Athens, GA nlazar@stat.uga.edu

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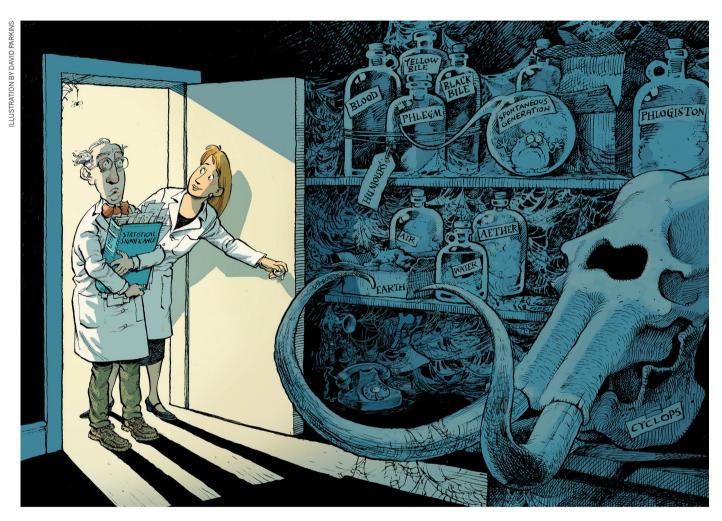
# COMMENT

**EVOLUTION** Cooperation and conflict from ants and chimps to us **p.308** 



HISTORY To fight denial, study Galileo and Arendt p.309 **CHEMISTRY** Three more unsung women — of astatine discovery **p.311** 

**PUBLISHING** As well as ORCID ID and English, list authors in their own script **p.311** 



# Retire statistical significance

Valentin Amrhein, Sander Greenland, Blake McShane and more than 800 signatories call for an end to hyped claims and the dismissal of possibly crucial effects.

hen was the last time you heard a seminar speaker claim there was 'no difference' between two groups because the difference was 'statistically non-significant'?

If your experience matches ours, there's a good chance that this happened at the last talk you attended. We hope that at least someone in the audience was perplexed if, as frequently happens, a plot or table showed that there actually was a difference.

How do statistics so often lead scientists to deny differences that those not educated in statistics can plainly see? For several generations, researchers have been warned that a statistically non-significant result does not 'prove' the null hypothesis (the hypothesis that there is no difference between groups or no effect of a treatment on some measured outcome)<sup>1</sup>. Nor do statistically significant results 'prove' some other hypothesis. Such misconceptions have famously warped the

literature with overstated claims and, less famously, led to claims of conflicts between studies where none exists.

We have some proposals to keep scientists from falling prey to these misconceptions.

#### PERVASIVE PROBLEM

Let's be clear about what must stop: we should never conclude there is 'no difference' or 'no association' just because a *P* value is larger than a threshold such as 0.05

or, equivalently, because a confidence interval includes zero. Neither should we conclude that two studies conflict because one had a statistically significant result and the other did not. These errors waste research efforts and misinform policy decisions.

For example, consider a series of analyses of unintended effects of anti-inflammatory drugs<sup>2</sup>. Because their results were statistically non-significant, one set of researchers concluded that exposure to the drugs was "not associated" with new-onset atrial fibrillation (the most common disturbance to heart rhythm) and that the results stood in contrast to those from an earlier study with a statistically significant outcome.

Now, let's look at the actual data. The researchers describing their statistically non-significant results found a risk ratio of 1.2 (that is, a 20% greater risk in exposed patients relative to unexposed ones). They also found a 95% confidence interval that spanned everything from a trifling risk decrease of 3% to a considerable risk increase of 48% (P = 0.091; our calculation). The researchers from the earlier, statistically significant, study found the exact same risk ratio of 1.2. That study was simply more precise, with an interval spanning from 9% to 33% greater risk (P = 0.0003; our

It is ludicrous to conclude that the statistically non-significant results showed "no association", when the interval estimate included serious risk increases; it is equally absurd to claim these results were in contrast with the earlier results showing an identical observed effect. Yet these common practices show how reliance on thresholds of statistical significance can mislead us (see 'Beware false conclusions').

These and similar errors are widespread. Surveys of hundreds of articles have found that statistically non-significant results are interpreted as indicating 'no difference' or 'no effect' in around half (see 'Wrong interpretations' and Supplementary Information).

In 2016, the American Statistical

Association released a statement in The American Statistician warning against the misuse of statistical significance and P values. The issue also included many commentaries on the subject. This month, a special issue in the same journal attempts to push these reforms further. It presents more than 40 papers on 'Statistical inference in the 21st century: a world beyond P < 0.05'. The editors introduce the collection with the caution "don't say 'statistically significant"33. Another article<sup>4</sup> with dozens of signatories also calls on authors and journal editors to disavow those terms.

We agree, and call for the entire concept of statistical significance to be abandoned.

"Eradicating categorization will help to halt **overconfident** claims. unwarranted declarations of 'no difference' and absurd statements about *'replication'* failure'."

We are far from alone. When we invited others to read a draft of this comment and sign their names if they concurred with our message, 250 did so within the first 24 hours. A week later, we had more than 800 signatories — all checked for an academic affiliation or other indication of present or past work

in a field that depends on statistical modelling (see the list and final count of signatories in the Supplementary Information). These include statisticians, clinical and medical researchers, biologists and psychologists from more than 50 countries and across all continents except Antarctica. One advocate called it a "surgical strike against thoughtless testing of statistical significance" and "an opportunity to register your voice in favour of better scientific practices".

We are not calling for a ban on *P* values. Nor are we saying they cannot be used as a decision criterion in certain specialized applications (such as determining whether a manufacturing process meets

some quality-control standard). And we are also not advocating for an anythinggoes situation, in which weak evidence suddenly becomes credible. Rather, and in line with many others over the decades, we are calling for a stop to the use of *P* values in the conventional, dichotomous way — to decide whether a result refutes or supports a scientific hypothesis<sup>5</sup>.

#### **QUIT CATEGORIZING**

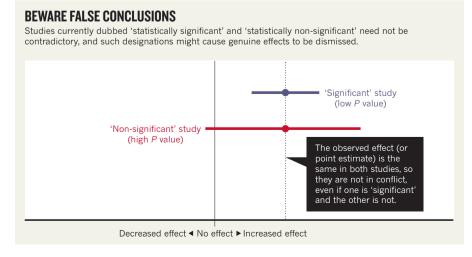
The trouble is human and cognitive more than it is statistical: bucketing results into 'statistically significant' and 'statistically non-significant' makes people think that the items assigned in that way are categorically different<sup>6-8</sup>. The same problems are likely to arise under any proposed statistical alternative that involves dichotomization, whether frequentist, Bayesian or otherwise.

Unfortunately, the false belief that crossing the threshold of statistical significance is enough to show that a result is 'real' has led scientists and journal editors to privilege such results, thereby distorting the literature. Statistically significant estimates are biased upwards in magnitude and potentially to a large degree, whereas statistically non-significant estimates are biased downwards in magnitude. Consequently, any discussion that focuses on estimates chosen for their significance will be biased. On top of this, the rigid focus on statistical significance encourages researchers to choose data and methods that yield statistical significance for some desired (or simply publishable) result, or that yield statistical non-significance for an undesired result, such as potential side effects of drugs — thereby invalidating conclusions.

The pre-registration of studies and a commitment to publish all results of all analyses can do much to mitigate these issues. However, even results from pre-registered studies can be biased by decisions invariably left open in the analysis plan<sup>9</sup>. This occurs even with the best of intentions.

Again, we are not advocating a ban on P values, confidence intervals or other statistical measures — only that we should not treat them categorically. This includes dichotomization as statistically significant or not, as well as categorization based on other statistical measures such as Bayes factors.

One reason to avoid such 'dichotomania' is that all statistics, including P values and confidence intervals, naturally vary from study to study, and often do so to a surprising degree. In fact, random variation alone can easily lead to large disparities in P values, far beyond falling just to either side of the 0.05 threshold. For example, even if researchers could conduct two perfect replication studies of some genuine effect, each with 80% power (chance) of achieving P < 0.05, it would not be very surprising for one to obtain P < 0.01 and the other P > 0.30.



Whether a *P* value is small or large, caution is warranted.

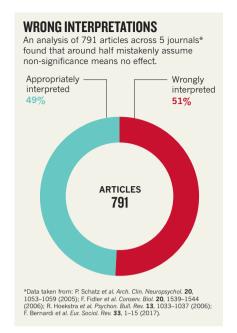
We must learn to embrace uncertainty. One practical way to do so is to rename confidence intervals as 'compatibility intervals' and interpret them in a way that avoids overconfidence. Specifically, we recommend that authors describe the practical implications of all values inside the interval, especially the observed effect (or point estimate) and the limits. In doing so, they should remember that all the values between the interval's limits are reasonably compatible with the data, given the statistical assumptions used to compute the interval<sup>7,10</sup>. Therefore, singling out one particular value (such as the null value) in the interval as 'shown' makes no sense.

We're frankly sick of seeing such nonsensical 'proofs of the null' and claims of non-association in presentations, research articles, reviews and instructional materials. An interval that contains the null value will often also contain non-null values of high practical importance. That said, if you deem all of the values inside the interval to be practically unimportant, you might then be able to say something like 'our results are most compatible with no important effect'.

When talking about compatibility intervals, bear in mind four things. First, just because the interval gives the values most compatible with the data, given the assumptions, it doesn't mean values outside it are incompatible; they are just less compatible. In fact, values just outside the interval do not differ substantively from those just inside the interval. It is thus wrong to claim that an interval shows all possible values.

Second, not all values inside are equally compatible with the data, given the assumptions. The point estimate is the most compatible, and values near it are more compatible than those near the limits. This is why we urge authors to discuss the point estimate, even when they have a large P value or a wide interval, as well as discussing the limits of that interval. For example, the authors above could have written: 'Like a previous study, our results suggest a 20% increase in risk of new-onset atrial fibrillation in patients given the anti-inflammatory drugs. Nonetheless, a risk difference ranging from a 3% decrease, a small negative association, to a 48% increase, a substantial positive association, is also reasonably compatible with our data, given our assumptions.' Interpreting the point estimate, while acknowledging its uncertainty, will keep you from making false declarations of 'no difference', and from making overconfident claims.

Third, like the 0.05 threshold from which it came, the default 95% used to compute intervals is itself an arbitrary convention. It is based on the false idea that there is a 95% chance that the computed interval itself contains the true value, coupled with the vague



feeling that this is a basis for a confident decision. A different level can be justified, depending on the application. And, as in the anti-inflammatory-drugs example, interval estimates can perpetuate the problems of statistical significance when the dichotomization they impose is treated as a scientific standard.

Last, and most important of all, be humble: compatibility assessments hinge on the correctness of the statistical assumptions used to compute the interval. In practice, these assumptions are at best subject to considerable uncertainty<sup>7,8,10</sup>. Make these assumptions as clear as possible and test the ones you can, for example by plotting your data and by fitting alternative models, and then reporting all results.

Whatever the statistics show, it is fine to suggest reasons for your results, but discuss a range of potential explanations, not just favoured ones. Inferences should be scientific, and that goes far beyond the merely statistical. Factors such as background evidence, study design, data quality and understanding of underlying mechanisms are often more important than statistical measures such as *P* values or intervals.

The objection we hear most against retiring statistical significance is that it is needed to make yes-or-no decisions. But for the choices often required in regulatory, policy and business environments, decisions based on the costs, benefits and likelihoods of all potential consequences always beat those made based solely on statistical significance. Moreover, for decisions about whether to pursue a research idea further, there is no simple connection between a *P* value and the probable results of subsequent studies.

What will retiring statistical significance look like? We hope that methods sections

and data tabulation will be more detailed and nuanced. Authors will emphasize their estimates and the uncertainty in them — for example, by explicitly discussing the lower and upper limits of their intervals. They will not rely on significance tests. When P values are reported, they will be given with sensible precision (for example, P=0.021 or P=0.13) — without adornments such as stars or letters to denote statistical significance and not as binary inequalities (P<0.05 or P>0.05). Decisions to interpret or to publish results will not be based on statistical thresholds. People will spend less time with statistical software, and more time thinking.

Our call to retire statistical significance and to use confidence intervals as compatibility intervals is not a panacea. Although it will eliminate many bad practices, it could well introduce new ones. Thus, monitoring the literature for statistical abuses should be an ongoing priority for the scientific community. But eradicating categorization will help to halt overconfident claims, unwarranted declarations of 'no difference' and absurd statements about 'replication failure' when the results from the original and replication studies are highly compatible. The misuse of statistical significance has done much harm to the scientific community and those who rely on scientific advice. P values, intervals and other statistical measures all have their place, but it's time for statistical significance to go. ■

Valentin Amrhein is a professor of zoology at the University of Basel, Switzerland.
Sander Greenland is a professor of epidemiology and statistics at the University of California, Los Angeles. Blake McShane is a statistical methodologist and professor of marketing at Northwestern University in Evanston, Illinois. For a full list of co-signatories, see Supplementary Information.

e-mail: v.amrhein@unibas.ch

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Supplementary information accompanies this article; see go.nature.com/2tc5nkm

# Exhibit 139

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1	IN THE UNITED STATES DISTRICT COURT
2	FOR THE DISTRICT OF NEW JERSEY
3	x
4	IN RE: JOHNSON & JOHNSON TALCUM
5	POWDER PRODUCTS MARKETING, SALES
6	PRACTICES, AND PRODUCTS MDL NO:
7	LIABILITY LITIGATION 16-2738 (FLW)(LHG)
8	x
9	THIS DOCUMENT RELATES TO
10	ALL CASES
11	x
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14	DEPOSITION UNDER ORAL EXAMINATION OF
15	SARAH E. KANE, M.D.
16	January 25, 2019, 9:19 a.m.
17	
18	
19	REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR
20	
21	GOLKOW TECHNOLOGIES, INC.
22	877.370.3377 ph   917.591.5672 fax
23	deps@golkow.com
24	
25	
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1		1	APPEARANCES: (Continued)
2		2	
3		3	SHOOK, HARDY & BACON L.L.P.
4		4	BY: HUNTER K. AHERN, ESQ.
5		5	701 Fifth Avenue, Suite 6800
6		6	Seattle, Washington 98104
7	Deposition of SARAH E. KANE, M.D.,	7	(206) 344-7600
8	held at the offices of Sugarman, Rogers,	8	hahern@shb.com
9	Barshak & Cohen, PC 363 Plantation Street, Boston,	9	Representing the Defendant, Johnson & Johnson,
10	Massachusetts, pursuant to Agreement before	10	Johnson & Johnson Consumer Companies, Inc.
11	Janet Sambataro, a Registered Merit Reporter,	11	voimbon & voimbon consumer companies, me.
12	Certified Realtime Reporter, Certified LiveNote		DRINKER BIDDLE AND REATH LLP
13	Reporter, and a Notary Public within and for the		BY: KATHERINE MCBETH, ESQ.
14	Commonwealth of Massachusetts, on January 25, 2019,	1	One Logan Square, Suite 2000
15	commencing at 9:19 a.m.		Philadelphia, Pennsylvania 19103-6996
16	Commencing at 9.19 a.m.		•
		16	(215) 988-2700
17		17	katherine.mcbeth@dbr.com
18		18	Representing the Defendant, Johnson & Johnson,
19		19	Johnson & Johnson Consumer Companies, Inc.
20		20	
21		21	GORDON & REES SCULLY MANSUKHANI, LLP
22		22	BY: MICHAEL R. KLATT, ESQUIRE
23		23	816 Congress Avenue, Suite 1510
24		24	Austin, Texas 78701
25		25	(512) 391-0197
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3	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ.		APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued)
3 4	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive	2 3 4	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants,
2 3 4 5	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410	2 3 4 5	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued)
3 4	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210	2 3 4 5 6	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants,
2 3 4 5 6 7	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600	2 3 4 5 6 7	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.
2 3 4 5 6 7 8	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com	2 3 4 5 6 7 8	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP
2 3 4 5 6 7 8	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600	2 3 4 5 6 7	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ.
2 3 4 5 6 7 8	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs	2 3 4 5 6 7 8 9	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue
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2 3 4 5 6 7 8 9	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs	2 3 4 5 6 7 8 9 10 11	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058
2 3 4 5 6 7 8 9 10	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs LEVIN PAPANTONIO	2 3 4 5 6 7 8 9 10 11	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com
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2 3 4 5 6 7 8 9 10 11 12 13	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St.	2 3 4 5 6 7 8 9 10 11 12 13	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com
2 3 4 5 6 7 8 9 10 11 12 13 14	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502	2 3 4 5 6 7 8 9 10 11 12 13 14	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW, LLC BY: JOHN RESTAINO, ESQ.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS LLP BY: MICHAEL ANDERTON, ESQ. 950 Main Avenue
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW, LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS LLP BY: MICHAEL ANDERTON, ESQ. 950 Main Avenue Cleveland, Ohio 44113
2 3 4 4 5 6 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW, LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street Denver, Colorado 80220	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS LLP BY: MICHAEL ANDERTON, ESQ. 950 Main Avenue Cleveland, Ohio 44113 (216) 592-5000
2 3 4 4 5 6 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW, LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street Denver, Colorado 80220 (303) 839-8000	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS LLP BY: MICHAEL ANDERTON, ESQ. 950 Main Avenue Cleveland, Ohio 44113 (216) 592-5000 michael.anderton@tuckerellis.com
2 3 4 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	APPEARANCES: HAUSFELD LLP BY: STEVE ROTMAN, ESQ. One Marina Park Drive Suite 1410 Boston, MA 02210 (617) 207-0600 srotman@hausfeld.com Representing the Plaintiffs  LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen St. Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW, LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street Denver, Colorado 80220	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	APPEARANCES: (Continued)  GORDON & REES SCULLY MANSUKHANI, LLP (Continued) Representing the Defendants, Imerys Talc America, Inc.  COUGHLIN DUFFY LLP BY: AMARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS LLP BY: MICHAEL ANDERTON, ESQ. 950 Main Avenue Cleveland, Ohio 44113 (216) 592-5000 michael.anderton@tuckerellis.com

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3	SEYFARTH SHAW LLP		Exhibit 9 Article entitled "Serous tubal
4	BY: THOMAS T. LOCKE, ESQ. (Via telephone)	4	intraepithelial carcinoma, chronic
	975 F Street, N.W.	5	fallopian tube injury, and serous
6	Washington, D.C. 20004	6	carcinoma development" 91
7	(202) 463-2400	7	Exhibit 10 "Blaustein's Pathology of the Female
8	Representing PCPC	8	Genital Tract," Fourth Edition 95
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1	EXHIBITS	1	identified yesterday in that list are voluminous
2		2	
3	Number Description Page		•
4	Exhibit 25 (Continued)	3	to the extent that they substantively informed
	and ovarian talc particle burden" 308	4	Dr. Kane's opinions in this case.
5	Exhibit 26 Article entitled "Pycnogenol reduces	5	We'd also like to object to the
6	Talc-induced Neoplastic Transformation	6	
7	in Human Ovarian Cell Cultures" 328	7	presentations, which were not intended for any
8		8	other purpose than for science day in the MDL.
9		9	And that's all I have to say on the
10		10	objections.
11		11	MR. ROTMAN: Go ahead.
12		12	MR. TISI: First of all, as you know,
13		13	many of those documents were documents that were
14		14	provided to counsel in connection with virtually
15		15	every depositions that have been taken to date.
16		16	In fact, it was provided with Dr. Mohrman that
17		17	was being taken at the same time today; it was
18		18	provided with Dr. Zelikoff earlier in the week;
19		19	it was provided almost routinely.
20		20	Many of them some of them,
21		21	particularly the Health Canada document, were
22		22	documents that only became available in mid
23		23	December, number one.
24		24	
			Number two, I believe that the science
25		25	day document that you're referring to, which I
	D 11	+	Daga 12
	Page 11		Page 13
1	PROCEEDINGS	1	_
1 2	PROCEEDINGS	1 2	think you'll find was not relied on in any way,
	PROCEEDINGS THE VIDEOGRAPHER: We are now on the		think you'll find was not relied on in any way, was a that was the California and not the MDL.
2 3	PROCEEDINGS THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a	2	think you'll find was not relied on in any way, was a that was the California and not the MDL. So I just want to be clear about that.
2 3 4	PROCEEDINGS THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.	2 3 4	think you'll find was not relied on in any way, was a that was the California and not the MDL. So I just want to be clear about that.  So there is no prejudice, and we would
2 3 4 5	PROCEEDINGS THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 25, 2019; the time,	2 3 4 5	think you'll find was not relied on in any way, was a that was the California and not the MDL. So I just want to be clear about that.  So there is no prejudice, and we would clearly object to these are not documents she
2 3 4 5	PROCEEDINGS THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 25, 2019; the time, 9:19 a.m.	2 3 4 5 6	think you'll find was not relied on in any way, was a that was the California and not the MDL. So I just want to be clear about that. So there is no prejudice, and we would clearly object to these are not documents she relied on for her report; they just are
2 3 4 5 6 7	PROCEEDINGS THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 25, 2019; the time, 9:19 a.m. This video deposition is being held in	2 3 4 5 6 7	think you'll find was not relied on in any way, was a that was the California and not the MDL. So I just want to be clear about that.  So there is no prejudice, and we would clearly object to these are not documents she relied on for her report; they just are supplemental materials. But you can ask
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- the first being with her report in November; the
   second being on January 4th, which was about ten
- <sup>3</sup> days before the deposition had been scheduled for
- <sup>4</sup> January 14th; and then these additional items
- <sup>5</sup> were materials that either were inadvertently
- left off or not reviewed until just very
   recently.
- 8 MS. AHERN: Okay. To the extent that
- <sup>9</sup> these new materials inform her substantive
- 10 opinions and were not included in her report or
- prior versions of the reference list, then we can
- 12 talk about that later --
- MR. TISI: Yeah.
- MS. AHERN: -- in terms of additional
- 15 time.
- And just to clarify, Steve, you said
- <sup>17</sup> that she reviewed one textbook. It looks like on
- 18 the list that I received, she reviewed the
- 19 second, fourth, and fifth editions of the
- 20 textbook --
- MR. ROTMAN: I was referring --
- MS. AHERN: -- or textbooks.
- MR. ROTMAN: I was referring to that as
- one textbook, yeah, but you're right, the
- <sup>25</sup> different editions. And she did bring with her
  - Page 15

- <sup>1</sup> today those materials.
- MS. AHERN: So she has a copy with her
- <sup>3</sup> today of all of the items listed in the
- <sup>4</sup> additional materials to Sarah Kane that was
- <sup>5</sup> served yesterday.
- 6 MR. ROTMAN: No.
- MS. AHERN: Okay. Do you know what
- she -- well, we can -- we'll find out.
- 9 MR. ROTMAN: Yeah.
- MS. AHERN: Okay. All right.
- SARAH E. KANE, M.D.,
- <sup>12</sup> having been duly sworn, after presenting
- identification in the form of a driver's license,
- <sup>14</sup> deposes and says as follows:
- DIRECT EXAMINATION
- <sup>16</sup> BY MS. AHERN:

25

- Q. Good morning, Dr. Kane.
- <sup>18</sup> A. Good morning.
- Q. Can you please state your name for the record?
- A. Sure. Sarah Kane.
- Q. And, Dr. Kane, who is your current employer?
- A. Commonwealth Pathology Partners.
  - Q. And do you have a business address at

- Page 16
- <sup>1</sup> Commonwealth Pathology Partners?
- A. The address we commonly use is 81
- <sup>3</sup> Highland Avenue, Salem, Massachusetts. It's <sup>4</sup> 01970.
- Q. Okay. And do you have any separate consulting business?
- A. No. Other -- outside of this type of
   medical expert witness work, no.
- Q. Okay. And how often do you do thissort of medical witness work?
- A. I am very new at it. I have done one deposition before in a tobacco case.
- Q. Okay. And the fees that you get from these cases, do they go directly to you or do
- they go to your -- Commonwealth PathologyPartners?
- A. They go directly to me.
- Q. And, Dr. Kane, you're a medical doctor; correct?
- <sup>20</sup> A. Yes.

- Q. And what is your medical specialty?
- A. I am board certified in anatomic and
- <sup>23</sup> clinical pathology and cytopathology, with
- <sup>4</sup> fellowship training in gynecologic pathology.
  - Q. Does that mean that you review
    - Page 17
- diagnostic materials, slides, and blocks that
- <sup>2</sup> have been taken from patient procedures and make
- <sup>3</sup> determinations regarding diagnosis?
  - A Yes
- Q. Do you see patients as part of your
- 6 medical practice?
- A. Yes. Occasionally, cytopathologists
- 8 sometimes perform a procedure that's called a
- <sup>9</sup> fine-needle aspiration. And so if a patient is
- seen in clinic and the clinician discovers a
- palpable nodule, I might be asked to go into the
- 12 room and perform a fine-needle aspiration.
  - Q. But you don't see patients in the sense that you don't counsel patients and provide ongoing care for an individual patient?
- A. Well, I mean, I guess my pathology
- 7 report is part of the -- basically speaks to
- <sup>18</sup> medical treatment and informs clinical treatment
- of the patient. So my pathology reports are seenby the patient.
- Q. I guess what I'm getting at is: Do you see patients as part of your practice, give them
- <sup>23</sup> a history and physical, provide ongoing care for
- them outside of the setting of a fine-needle
- <sup>25</sup> aspiration or a specific procedure related to a

Page 20 Page 18 <sup>1</sup> diagnosis? <sup>1</sup> aspiration, a blood transfusion reaction. 2 MR. ROTMAN: Is this working for you? Are there any others? 3 THE WITNESS: Oh, I'm sorry? A. I'm trying to think what another MR. ROTMAN: Is it working? 4 possibility might be. 5 THE WITNESS: Yes. I mean, I go into the operative room when 6 patients are in surgery sometimes with the MR. ROTMAN: Okay. A. Outside of the fine-needle aspiration surgeon to do intraoperative frozen sections, setting, the only time I might see a patient which are realtime diagnosis while the patient is would be with a blood transfusion reaction. I having a procedure. 10 might have to go to the floor to examine the Q. But you're interacting with the <sup>11</sup> patient or patient chart. physicians in that respect, aren't you, not with 12 Ongoing care for them outside of the setting the patient? 13 13 of a fine-needle aspiration, the nature of A. It can be both. 14 gynecologic pathology, sometimes I will see a Pap 14 MR. ROTMAN: Objection. Objection. 15 15 smear from a patient and then a cervical biopsy You can answer. <sup>16</sup> from a patient and then a LEEP from the patient, 16 MS. AHERN: You can answer. <sup>17</sup> and I might speak to the clinician about 17 A. The vast majority of the time I'm with 18 treatment algorithms, that kind of thing. frozen sections, I'm interacting with the 19 Q. Do you actually then go see the patient 19 surgeon. 20 themselves and discuss with them the results of 20 Q. Are there times where you are 21 their Pap smear or other testing? interacting with the patient during a surgical 22 A. Typically, no. procedure? 23 Q. Have you ever performed a history and 23 MR. ROTMAN: When you say physical in your practice as a pathologist? <sup>24</sup> "interacting," you mean having a conversation or A. Yes. do you mean having any kind of contact? Page 19 Page 21 Q. Under what circumstances? MR. KLATT: Steve, just limit the 1 2 <sup>2</sup> objection to "form." A. Under blood transfusion reactions. Q. And what sort of history and physical MR. ROTMAN: I'm trying to clarify. MR. KLATT: It doesn't matter. <sup>4</sup> do you take in relation to a blood transfusion reaction? BY MS. AHERN: A. Well, you might be looking at blood Q. Did you understand -pressure and review of the medical chart, MR. KLATT: Object to form. temperature, that kind of thing. Q. -- the question, Doctor? 9 O. So you review the medical chart. A. Let me -- can -- I'm sorry. Can you 10 Is that medical chart prepared by another 10 read it back or --11 11 Q. You said, "The vast majority of" -physician? 12 12 MR. ROTMAN: She's reading, I think. A. Usually, you're looking at 13 13 retrospective data at the time of the blood MS. AHERN: I'll withdraw the question transfusion reaction. and just remind you. 15 Q. How often will you see the same patient BY MS. AHERN: who has had a blood transfusion reaction? 16 Q. You said that the vast majority of the 17 A. Not very often. time you're interacting with the physicians; 18 Q. Okay. Do you ever counsel patients on 18 correct? 19 risk factors for ovarian cancer? A. Yes. 20 A. Have I ever? Probably, but in my Q. What do you mean by "interacting"? <sup>21</sup> day-to-day practice, I'm not seeing patients on a A. During the surgery, the surgeon might <sup>22</sup> regular basis to do that. 22 have me come up to the operative room or the Q. And the only time you see patients is 23 surgeon might come down to look at the tissue,

<sup>24</sup> with regard to specific issues that are within

<sup>25</sup> your realm of pathology expertise, a fine-needle

both grossly and under the microscope with me.

Q. Okay. Under those circumstances, would

1 you ever speak to the patient?

A. Usually not.

2

- Q. And if you -- have you ever spoken to a patient when you were reviewing frozen sections?
  - A. I might have during rapid reads of
- <sup>6</sup> fine-needle aspirations. So sometimes
- <sup>7</sup> interventional radiologists will do fine-needle
- 8 aspirations if they have to be ultrasound guided.
- <sup>9</sup> So, yes, I'm speaking to patients sometimes in
- 10 that situation and, obviously, when I do
- <sup>11</sup> fine-needle aspirations.
- 12 Q. Okay. But you don't have a group of patients that come to you for ongoing care and <sup>14</sup> see you in an office setting, do you?
- A. They are basically -- I would say it's <sup>16</sup> the equivalent of physician referral. So if a --<sup>17</sup> if a clinician is doing a biopsy -- I mentioned
- women with Pap smears and then cervical biopsies
- and then cone LEEPs, you know, it's a trajectory
- <sup>20</sup> of care, but it's physician referred for tissue.
- 21 Q. When you say "physician referred," what
- 22 do you -- what do you mean by that? Are you <sup>23</sup> interacting with the physician in providing
- <sup>24</sup> advice or recommendations or are you interacting
- <sup>25</sup> with the patients themselves and providing advice
  - Page 23

- <sup>1</sup> or recommendations?
- A. The physicians usually.
- 3 Q. Okay. So I'm asking about patients.
- A. Yeah.
- Q. On a given day -- like what are -- what 6 are the days that you're in the office?
  - A. Monday through Friday.
- Q. So are there days that you do 8
- particular tasks, administrative, and then days
- 10 that you do frozen sections or days that you do
- <sup>11</sup> just general pathology reads?
- 12 A. Rarely, I have an administrative day.
- 13 It would be nice to have more, but, typically, I
- <sup>14</sup> am looking at slides the majority of the day.
- I will be doing frozen sections on some <sup>16</sup> days, but we have a very collegial atmosphere, so
- 17 I might do frozens with another pathologist.
- <sup>18</sup> Some days I'm on cytology, so I'm doing the
- <sup>19</sup> fine-needle aspirations, which is either me
- <sup>20</sup> performing the fine-needle aspirations or me
- <sup>21</sup> reading a rapid interpretation that an
- <sup>22</sup> interventional radiologist has performed.
- Q. So on -- in a given week, it's not like
- you have a patient clinic where patients come to
- 25 see you and they're scheduled to see you.

- A. That's correct. They're not scheduled to see me.
- Q. Okay. And so outside of, like you
- mentioned, procedures like a fine-needle
- aspiration, you wouldn't generally see patients
- <sup>6</sup> directly.
- A. The fine-needle aspiration would be the
- only setting where they would have a scheduled,
- allotted slot time with me.
- Q. Okay. Generally speaking, when you're reviewing slides, what sort of medical records do
- you have available to you that are relevant to
- your clinical diagnosis?
  - A. I have the entire medical record
- available to me, whatever is in the hospital
- system for that patient.
- Q. What do you routinely rely on or review as part of your review of slides in terms of
- medical records?
- 20 A. Well, it's very patient dependent and
- <sup>21</sup> very diagnosis dependent, but, for example --
- <sup>22</sup> I'll stick to the example of cervical biopsy. So
- <sup>23</sup> I'll be looking -- if I have a cervical biopsy,
- <sup>24</sup> I'll look to see the patient's history of Pap
- <sup>25</sup> smears, HPV tests, that kind of thing.
- Page 25
- Q. Documents that are directly relevant to
- <sup>2</sup> your review of the current pathology; is that correct?
- A. For the most part, I would say so.
- Q. In other words, you don't go back
- through all of their physician records or
- gynecologic visits, their primary care physician
- records?
- A. Again, it would depend on the
- situation. I mean, if I have a lung tumor case,
- I'll probably be looking at the radiology, the
- radiology reports, the -- I'll pull up a report
- with a primary care physician to look for smoking
- history, that kind of thing, to put the whole
- piece together for the diagnosis.
- 16 Q. Okay. And, Doctor, you're here today to provide a deposition as an expert witness on
- behalf of the plaintiffs; is that correct?
- 19
  - A. Yes.

22

- 20 Q. And you said you've given one
- 21 deposition in the past?
  - A. Yes, that's correct.
- 23 Q. And what sort of case was that?
- 24 A. That was a tobacco case.
  - Q. Were you an expert in that case?

<sup>1</sup> A. Yes. It was an individual causation <sup>2</sup> case.

<sup>3</sup> Q. Okay. Were you an expert for the <sup>4</sup> plaintiffs or the defendants?

A. For the plaintiffs.

5

Q. And what sort of -- what sort of case was that in terms of the injury that was being alleged?

<sup>9</sup> A. It was a patient with lung cancer who was suing a tobacco company.

Q. And what was your specific -- what was your opinion in that case?

A. That it was highly likely that her long history of smoking caused her lung cancer.

Q. So -- and I should have gone over this with you in the beginning, but you're familiar with the deposition rules?

8 A. In general, I think.

<sup>19</sup> Q. Okay. You're doing a very good job.

<sup>20</sup> And the main things to remember is the two of us

 $^{21}$  will try not to speak over each other so that the

court reporter can take a clean transcript down.
 If you need a break at some time, that's

If you need a break at some time, that's
 fine, just let me know. All I ask is if there's

<sup>25</sup> a question pending, you go ahead and finish the

Page 26 MS. AHERN: You're welcome.

<sup>2</sup> BY MS. AHERN:

<sup>3</sup> Q. Dr. Kane, I've handed you a copy of

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<sup>4</sup> your Notice of Deposition for today.

5 Have you seen this document before?

6 A. Yes.

Q. When did you see it?

8 A. I believe it was sometime in December,

<sup>9</sup> because the original deposition date was

<sup>10</sup> January 14th.

Q. And, Doctor, do you know whether you produced all of the documents that are responsive to the request in Exhibit 1, your deposition

4 notice?

MR. ROTMAN: We've objected to a number of them. And so she's producing -- you should go

17 item by item, I think, if you want to -- I'm

18 going to object otherwise.

Q. Doctor, do you know what you brought with you today?

A. Yes. We have my -- a copy of my

<sup>22</sup> updated CV. We have copies of my invoice. I

<sup>23</sup> believe I have a copy of -- oh, right. Sorry.

I have pages that I found for the Blaustein

second edition, which I don't have the actual

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- $^{\mbox{\scriptsize 1}}\,$  answer to the question and then we'll take a
- <sup>2</sup> break.

<sup>3</sup> If you don't understand a question that I

<sup>4</sup> ask you, please don't answer it. Let me know

<sup>5</sup> that you don't understand the question or you'd

6 like me to rephrase it and I'll be happy to do

<sup>7</sup> that. All right?

8 A. Okay.

<sup>9</sup> Q. Okay. And if you answer the question,

 $^{10}$  is it fair for me to assume that you understood

11 it?

14

- 12 A. Yes.
- Q. All right.

(Notice of Oral and Videotaped

Deposition of Sarah E. Kane and Duces Tecum
 marked Exhibit 1.)

17 BY MS. AHERN:

Q. Doctor, I'm handing you what's been marked as Exhibit No. 1 to your deposition.

MS. AHERN: I don't know how many

<sup>21</sup> people need copies of these. I don't have that

22 many, but --

MR. TISI: I'll take a copy. Thank

24 you.

25

MR. ROTMAN: Thank you.

<sup>1</sup> textbook. I believe I got -- I found this image

<sup>2</sup> off of the internet. But I do have the fourth

<sup>3</sup> and fifth editions of the Kurman Blaustein's

<sup>4</sup> textbook, and I've marked any relevant pages that

<sup>5</sup> I reviewed a couple of days ago.

MS. AHERN: If you --

7 MR. ROTMAN: One second.

8 MS. AHERN: It might be easier if you

<sup>9</sup> just hand me those and let me take a look.

MR. ROTMAN: In addition, there's the

boxes in the room that are the documents that

<sup>12</sup> were sent up by counsel from Ashcraft & Gerel.

MS. AHERN: Thank you.

BY MS. AHERN:

13

Q. All right, Doctor. So let's take these

<sup>16</sup> in order, I guess. Let's look at your --

MR. ROTMAN: She also has a copy of her report.

MS. AHERN: Okay. We'll mark your updated CV as Exhibit No. 2.

(Curriculum vitae of Sarah E.

Kane, M.D. marked Exhibit 2.)

23 BY MS. AHERN:

Q. Do you need a copy in front of you?

A. Sure.

- 1 Q. Okay.
- MS. AHERN: I don't know if anyone else
- <sup>3</sup> needs a copy.
- <sup>4</sup> BY MS. AHERN:
- Q. Doctor, Exhibit 2, this is a copy of
- 6 your current curriculum vitae?
- A. Yes. January 2019, yes, this is the
- 8 current.
- <sup>9</sup> Q. And can you tell me what has been
- 10 updated since you submitted your report
- <sup>11</sup> November 15th of 2018?
- A. I believe the only change is that I am
- 13 now director of cytopathology at North Shore
- 14 Medical Center, which includes Salem Hospital and
- <sup>15</sup> Union Hospital, which is in Lynn, Massachusetts.
- Q. Are there any additional publications
- 17 that you have included on your updated resume --
- 18 or, sorry, updated CV?
- <sup>19</sup> A. I don't believe so.
- Q. The only change is that your position
- <sup>21</sup> has changed to director?
- A. Yes, of cytopathology.
- Q. Okay. And you've also brought with you
- 24 invoices --
- 25 A. Yes.

- <sup>1</sup> June 16th, which is the last date. So it would
  - <sup>2</sup> have been after June 16th, 2017.
  - Q. I'm sorry. Do you remember when you
  - 4 were retained by the plaintiffs to be an expert
  - <sup>5</sup> in this litigation?
  - A. I believe I was contacted by Mr. Rotman
  - <sup>7</sup> in early May of 2017.
  - 8 Q. Okay. Do you know how Mr. Rotman found

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- <sup>9</sup> your name?
- A. I believe he was referred by a
- 11 colleague.

12

13

15

21

- Q. Do you remember what colleague that is?
- A. Dr. Paul Michaels.
- Q. And is Dr. Michaels a pathologist?
  - A. Yes.
- Q. Where does Dr. Michaels work?
- A. I actually don't know the name of his
- 18 group, but he is in Austin, Texas now.
- <sup>19</sup> Q. Where was he in 2017?
- A. Austin, Texas, I believe.
  - Q. Okay. Is he a gynecologic pathologist?
- 22 A. No.
- Q. What type of pathologist is he?
  - A. He has a cytopathology fellowship, in
- <sup>25</sup> addition to anatomic and clinical board

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- Q. -- for your time spent on talc?
- <sup>2</sup> A. I handed them to her. Yes.
- MR. ROTMAN: What we handed, I think,
- <sup>4</sup> is multiple copies, so you can hand one back, I
- <sup>5</sup> suppose.
- 6 MS. AHERN: We'll mark as Exhibit 3 to
- <sup>7</sup> your deposition an invoice for rendered services.
- 8 (Invoice from Sarah Kane, M.D.,
- 9 for services 5/19 through 7/14 marked
- Exhibit 3.)
- MS. AHERN: I can't see a date, but it
- 12 looks like it covers -- well, let's just have you
- 13 look at it.
- 14 BY MS. AHERN:
- Q. Can you tell me the date range covered
- 16 by that invoice?
- MR. ROTMAN: Copy for me?
- A. Yes. It looks like it is from May 19th
- <sup>19</sup> to June 16th. That would be -- if this is the
- <sup>20</sup> first invoice, I believe, that would be of 2017,
- <sup>21</sup> year 2017.
- Q. Okay. And, Doctor, was this May 19,
- <sup>23</sup> 2017 -- how long after you were retained did you
- 24 submit this invoice?
- A. I wouldn't have sent it until after

<sup>1</sup> certification.

- Q. And how do you know Dr. Michaels?
- 3 A. We were residents and fellows together.
- 4 Q. Were you -- fellows where? Mass
- 5 General?
- 6 A. At Massachusetts General, yes.
- Q. Was he in the gynecologic pathology
- 8 fellowship with you or a different fellowship?
- A. So my fellowship was kind of
- 10 interesting. I was, unfortunately, one of the
- 11 last groups where a combined anatomic and
- 12 clinical pathology residency was five years. I
- 13 think the next year after I began residency they
- <sup>14</sup> dropped it to four years.
- So my surgical pathology and cytopathology,
- 16 it was a two-year fellowship. The gyn path and
- the cytopathology, it was over a two-year period.
- 18 And the weeks of gynecologic pathology were mixed
- with weeks of cytopathology, so they spread out
- 20 the cytopathology fellowship over two years.
- Paul was a cytopathology fellow the first
- 22 year of my fellowship, so we did all four years
- of anatomic and clinical pathology and then the
- <sup>24</sup> first year of fellowship at the same time.
- Q. Okay. And looking back at Exhibit 3,

- 1 this invoice from May 19, 2017, to July 14 of
- <sup>2</sup> 2017, the first entry looks like it's -- it
- <sup>3</sup> covers a period of May 19th through July 14th,
- 4 "Communication with firm regarding talc
- <sup>5</sup> litigation case, one hour"; is that correct?
- A. Yes. Sorry. Thank you for correcting
- 7 me. I saw the last line, 6/16, and figured that
- 8 was the last day that this covered. But you're
- <sup>9</sup> correct, it's -- July 14th would have been the
- 10 last date that this invoice covered.
- 11 Yes, June 16th I met with Mr. Rotman,
- 12 Dr. Thompson, and Mr. Soileau -- I don't know how
- 13 to pronounce his last name.
- 14 Q. Are they all -- they're all attorneys;
- 15 correct?
- 16 A. Correct.
- 17 Q. Okay. What firm?
- A. I know Mr. Rotman is with Hausfeld.
- 19 Dr. Thompson is with Allen Beasley. I don't know
- for sure where Mr. Soileau is from.
- 21 Q. You said Mr. Thompson is with Beasley
- 22 Allen.
- 23 A. I believe so. I don't remember for
- 24 certain.
- 25 Q. And at least during --

- So those hours overlap a little bit. I
- <sup>2</sup> mean, I kept track of particular hours so that I

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- <sup>3</sup> could bill accurately, but those two things --
- 4 certainly, generating the medical expert report
- would also include review of medical literature.
- Q. Okay. So you started on your -- on the
- draft of your expert report in this case back in
- May of 2017; is that correct?
  - A. Late May, yes.
- Q. And did you -- do you remember when you
- started your review of the medical literature?
- 12 Would it have been May 20th, as reflected in this
- invoice, Exhibit 3?
- 14 A. Yes, I believe so.
  - Q. You also have on here that you spent
- some time researching electron microscopy
- experts.

15

18

- A. Yes.
- 19 Q. Was that at the request of the
- plaintiffs' counsel?
- 21 A. Plaintiffs' counsel was looking for
- additional people because there are very few
- electron microscopy units in the country and very
  - few expert electron microscopists.
  - I can't remember if they asked me to or I

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- 1 MR. ROTMAN: It's Ms. Thompson.
- 2 MS. AHERN: Ms. Thompson.
- MR. ROTMAN: Or Dr. Thompson. 3
- THE WITNESS: Doctor. She's a -- she's
- a doctor, as well as an attorney.
- 6 Q. And for this first invoice, you billed
- 7 \$26,666.67; correct?
- 8 A. Yes.
- 9 Q. And you spent a total of 53 hours and
- <sup>10</sup> 20 minutes working on talc-related issues?
- 11 A. Yes.
- 12 Q. Seventeen hours and five minutes of
- 13 that was reviewing the medical literature, expert
- reports, and testimony; is that correct?
- A. So this was my first time ever
- <sup>16</sup> recording any sort of invoice for medical expert
- witness work, so the review of medical
- <sup>18</sup> literature, expert reports, and testimony,
- 19 probably some of that will also be included in
- <sup>20</sup> the generating of medical expert report, because
- <sup>21</sup> while I was -- I basically began -- you can see
- <sup>22</sup> from the dates I pretty much started drafting,
- 23 taking notes in a draft, around May 28th, which
- <sup>24</sup> was soon after I did my initial medical
- <sup>25</sup> literature searches.

- <sup>1</sup> offered to. It could have been the latter. But
- <sup>2</sup> I was aware that they were looking for additional
- people to potentially use electron microscopy.
- Q. Do you know how plaintiffs intended to
- use the electron microscopy experts?
- MR. ROTMAN: Objection. That's going
- into areas that you're not entitled to, so she's
- not going to answer that.
- BY MS. AHERN:
- Q. Doctor, what sort of electron
- microscopists were you looking for at the
- plaintiffs' request?

- MR. ROTMAN: Same objection.
- MS. AHERN: I'm not asking her about
- communications that she had with counsel; I'm
- 16 asking her what sort of work --17
  - MR. ROTMAN: Your question --
- 18 MS. AHERN: -- she did --19
  - MR. ROTMAN: Your question --
- MS. AHERN: -- that she was paid for by
- the plaintiffs' counsel and that's reflected on
- the invoice that you've submitted here today.
- MR. ROTMAN: You are asking her what she was doing at plaintiffs' counsel's request.
- 25 That's unrelated to her --

Page 40 Page 38 1 MS. AHERN: You're --<sup>1</sup> P-E-T-U-R. 2 MR. ROTMAN: -- opinions. Q. N-I-E-, Nielsen? 3 MS. AHERN: -- instructing her not to 3 A. I believe so. 4 answer the question of, "Doctor, what sort of Q. -S-S-O-N? electron microscopists were you looking for at A. No, -L-S-E-N. plaintiffs' request?" Q. Did you speak to Dr. Nielsen about MR. ROTMAN: Yes. I'm objecting to potentially working on the talc litigation? 8 that. A. I believe I e-mailed him. 9 Q. Do you remember when that occurred? MR. KLATT: That's not a communication. A. It was probably -- I don't remember 10 MS. AHERN: That's not a communication. 11 That is what did she do and what was she looking exactly, but I would imagine it was between 5/22 and 6/1 of 2017. <sup>12</sup> for. 13 13 MR. TISI: It's consulting. Q. And was he interested in doing any talc MS. AHERN: She's sitting here today as 14 14 work? 15 <sup>15</sup> a testifying expert. A. He was not interested in doing medical 16 MR. ROTMAN: Understood. She's not expert witness or consulting work. Q. Did you e-mail anybody else, any other going to answer that. BY MS. AHERN: electron microscopists? MR. ROTMAN: So you keep on asking her 19 Q. Doctor, did you make any <sup>20</sup> recommendations regarding electron microscopists? <sup>20</sup> about the consulting work that she was doing that 21 A. No, ultimately, I did not give them any 21 had nothing to do with her opinions in this case, <sup>22</sup> which is why we're here today. We're not here 22 names. 23 23 today for you to take the deposition of her Q. What electron microscopists were you <sup>24</sup> looking at when you were conducting your <sup>24</sup> consulting work at that stage on this issue, so 25 that whole area is off limits and I'm instructing 25 research? Page 39 Page 41 <sup>1</sup> her not to answer. If you want to continue MR. ROTMAN: Again, this is her work <sup>2</sup> on -- as a consultant not relating to her <sup>2</sup> asking those questions, I'm going to continue to opinions in this case --<sup>3</sup> object on the same basis. Q. Doctor, did you contact any electron Q. Doctor, do you --MR. ROTMAN: -- so you're not entitled microscopists who agreed to work on the talc <sup>6</sup> to this information. litigation? 7 MS. AHERN: You're instructing her not MR. ROTMAN: Objection. 8 Instruct you not to answer for the to answer. 9 MR. ROTMAN: Yes. reasons previously provided. 10 10 Q. Doctor, do you know a Dr. Campion? MS. AHERN: Then instruct her not to 11 11 A. I do not. answer. 12 12 MR. ROTMAN: I'm instructing you not to Q. Do you know a Dr. John Godleski? 13 A. I know the name. I do not know him 13 answer. 14 THE WITNESS: Okay. personally. 15 15 BY MS. AHERN: Q. Do you know Bill Welch? 16 16 Q. Doctor, do you know any electron A. I know the name. I do not know him microscopists? 17 17 personally. 18 A. Yes. 18 Q. Okay. 19 19 Q. Who? (Invoice from Sarah Kane, M.D., A. I know Dr. Gunnlaugur Nielsen at 20 for services 7/28 through 9/12 marked <sup>21</sup> Massachusetts General Hospital. 21 Exhibit 4.) Q. How do you spell Gunnlaugur's name? 22 BY MS. AHERN: 23 23 A. G-U-N-N -- I believe there are two Q. Doctor, I'm handing you what's been <sup>24</sup> Ns -- L-A-U-G-H-E-R [sic], Nielsen. That's with 24 marked as Exhibit 4 to your deposition. 25 <sup>25</sup> an S-E-N. But he goes by Petur, which is Can you tell me what that is?

- A. This is probably the second invoice.
- <sup>2</sup> Again, I don't believe I had it numbered on the
- <sup>3</sup> actual invoice, but this looks like it would be
- <sup>4</sup> the second invoice.
- Q. And what period of time does Exhibit 4cover?
- A. This covers July 28th to September 12.
- <sup>8</sup> Q. Is this 2017?
- 9 A. Yes.

1

- Q. And you spent an additional 37 hours
- and 40 minutes reviewing literature and
- generating your expert report; is that correct?
- A. Right. And you'll see I actually
- 14 combined everything, because it got too
- 15 complicated to separate them out. And generating
- <sup>16</sup> the medical expert report was sort of this
- <sup>17</sup> organic part of reviewing the literature.
- <sup>18</sup> Q. And the total bill was for \$19,666.67;
- 19 correct?
- 20 A. Yes.
- Q. Okay. Was all your time on Exhibit 4
- <sup>22</sup> spent working on your MDL report?
- A. I'm sorry. This invoice?
- Q. Yes, ma'am. Was the time spent on
- <sup>25</sup> Exhibits 3 and 4, these first two invoices, was

- Page 44
- Q. Who's been your primary contact?
   A. Mr. Rotman.
- <sup>3</sup> Q. Okay. And a total for that bill was
- 4 \$13,835; is that correct?
- <sup>5</sup> A. Yes.
- <sup>6</sup> (Invoice from Sarah Kane, M.D.,
- <sup>7</sup> for services 2/23/18 through 8/3/18 marked
- 8 Exhibit 6.)
- <sup>9</sup> BY MS. AHERN:
- O Q. I'm handing you what's been marked as
- <sup>11</sup> Exhibit 6 to your deposition.
- 12 Can you tell me what that document is,
- 13 please?
- A. So this -- I'm counting now -- looks
- 15 like this is the fourth invoice -- yes, the
- <sup>16</sup> fourth invoice that I sent them.
- Q. And what period of time does this
- <sup>18</sup> Exhibit 6 cover?
- A. It looks like February 23rd, 2018,
- <sup>20</sup> through August 7th, 2018.
  - Q. Okay. And Exhibit 6 reflects that you
- <sup>22</sup> spent an additional 16 hours and 55 minutes
- 23 reviewing literature and generating your medical

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- <sup>24</sup> expert report; is that correct?
- A. Yes.

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- <sup>1</sup> this all in relation to your work on the talc
- <sup>2</sup> MDL?
- <sup>3</sup> A. Yes. I'm not involved in any other
- <sup>4</sup> talc litigation.
- <sup>5</sup> Q. Okay.
- MS. AHERN: Okay. I'm marking
- <sup>7</sup> Exhibit 5 as -- oh, I'm marking, sorry, your
- 8 third invoice as Exhibit 5 to your deposition.
- <sup>9</sup> (Invoice from Sarah Kane, M.D.,
- for services 9/18/17 through 2/5/18 marked
- <sup>11</sup> Exhibit 5.)
- 12 BY MS. AHERN:
- Q. This is a copy of an invoice submitted
- 14 by you; correct?
- 15 A. Yes.
- Q. And what dates does it cover?
- A. This covers September 18th, 2017, to
- <sup>18</sup> February 5th, 2018.
- Q. You spent an additional 27 hours and 40
- <sup>20</sup> minutes working on your report; is that correct?
- A. Yes. Well, 21 hours, 55 minutes
- <sup>22</sup> reviewing the literature and the medical expert
- <sup>23</sup> witness report, and then there were a few hours
- <sup>24</sup> communicating and meeting with the firm, which
- <sup>25</sup> would likely be Mr. Rotman.

- Q. And 3 hours and 30 minutes
- <sup>2</sup> communicating or meeting with the law firms
- <sup>3</sup> involved.
  - A. Correct.
- <sup>5</sup> Q. Okay. And the total for that invoice
- 6 was \$10,208; correct?
  - A. Correct.
  - Q. Okay. I'm handing you what's been
- <sup>9</sup> marked as Exhibit 7 to your deposition.
  - (Invoice from Sarah Kane, M.D.,
- <sup>11</sup> for services 9/20/18 through 11/16/18
- marked Exhibit 7.)
- 13 BY MS. AHERN:
- Q. And this is another invoice prepared by
- 15 you?

20

25

- 16 A. Yes.
- Q. And the period of time that is covered
- appears to be September 20th, 2018, through
- <sup>19</sup> November 16th of 2018; is that right?
  - A. Yes.
- Q. And you spent an additional 71 hours
- and 5 minutes reviewing materials and generating
- <sup>23</sup> your expert report?
- <sup>24</sup> A. Yes.
  - Q. And about four-and-a-half hours

1 communicating with the law firms involved?

- <sup>2</sup> A. That's correct.
- <sup>3</sup> Q. For a total of \$37,791.67?
- 4 A. Yes.
- <sup>5</sup> Q. Doctor, do you have any -- this takes
- 6 us through -- this last invoice, Exhibit 7, takes
- <sup>7</sup> us through November of 2018.
- 8 You've done additional work since November
- 9 of 2018; correct?
- 10 A. I have.
- Q. Do you know how much time you have yet
- 12 to invoice or -- sorry, let me back up. Withdraw
- 13 that.
- Have you sent another invoice to plaintiffs'
- 15 counsel?
- 16 A. I have not.
- Q. Okay. Do you have any idea how many
- 18 hours you have yet to invoice?
- A. I have not added it up. I don't really
- 20 have a ballpark. Maybe -- I would just be
- 21 guessing. I haven't added it up, to be honest.
- Q. Do you know how much money you've made
- <sup>23</sup> to date, totaling all of these together?
- 4 MR. ROTMAN: Objection.
- Q. How much money -- how much money have

- <sup>1</sup> and produce it to one of the attorneys involved?
- 2 A. Sure.
- <sup>3</sup> Q. Thank you.
- 4 MR. ROTMAN: She'll find it if it
- <sup>5</sup> exists. She'll look for it.
  - MS. AHERN: Clearly.
- 7 MR. ROTMAN: She didn't testify that
- 8 she produced a fee schedule; she said she
- believed she did.
- MS. AHERN: Understood. If she finds
- <sup>11</sup> it --
- MR. ROTMAN: Yeah.
- MS. AHERN: -- she'll produce it to you
- <sup>14</sup> and you'll produce it to us.
- MR. ROTMAN: Exactly.
- 16 BY MS. AHERN:
- Q. Doctor, how much -- I mean, how do you
- 18 keep track of your time? Do you have a
- 19 spreadsheet? Do you have some process where you
- log your hours?
- A. I keep a list, an electronic list.
- <sup>22</sup> It's not an Excel, but it's just a list.
- Q. So is it just a Word document and you
- 24 put your time entries in and multiply that by
- <sup>25</sup> your hourly rate?

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- $^{\, 1} \,$  you made in fees associated with your talc work
- <sup>2</sup> to date?
- <sup>3</sup> A. I would need a calculator to add it all
- <sup>4</sup> up, but this would be the full amount, all added
- <sup>5</sup> together.
- <sup>6</sup> Q. And, Doctor, you're charging \$500 an
- <sup>7</sup> hour; correct?
- 8 A. Yes.
- <sup>9</sup> Q. Did you ask for a retainer when you
- <sup>10</sup> were initially asked to get involved in the case?
- <sup>11</sup> A. I did not.
- Q. Were you offered a retainer?
- <sup>13</sup> A. It wasn't discussed.
- Q. Does the amount that you charge or your
- 15 fee, does that change with the activity that
- <sup>16</sup> you're performing?
- A. No. I think I had a fee schedule where
- trial might be on a per-day basis, but I don't
- <sup>19</sup> remember what that is.
- Q. Did you actually submit a written fee
- schedule to the plaintiffs' counsel?
   A. I believe I did at some point.
- MR. ROTMAN: I don't know. I don't
- <sup>24</sup> recall that.

25

Q. Could you find a copy of that, please,

- A. Basically.
- 2 Q. And do you generate the invoices
- <sup>3</sup> yourself?
- 4 A. I do.
- Q. Is that through some sort of program or
- <sup>6</sup> is this just a Word document that you created and
- <sup>7</sup> you plug the information in?
  - A. It's just a Word document.
- 9 (Discussion off the record.)
- 10 BY MS. AHERN:

16

25

- Q. So, Doctor, other than the folders that
- <sup>12</sup> we've just gone through, is there anything
- 13 related to your opinions in this case that you
- did not bring with you to the deposition today?
- MR. ROTMAN: Objection.
  - Q. Start with that.
- MR. ROTMAN: Objection.
- A. I believe I brought all of the
- 19 literature cited in the initial reports. I've
- <sup>20</sup> tried to be complete, as you know, with listing
- <sup>21</sup> everything that I've reviewed. It's possible
- there might have been some things that I reviewed
- 23 that I forgot to put on a list, but I've tried to
- <sup>24</sup> be as complete as possible.
  - Q. How did you track your literature

Page 50 1 reviews? MR. KLATT: Chris, let me just clarify. A. So when I was writing the report, <sup>2</sup> There's four blue cardboard TLS boxes --<sup>3</sup> you'll notice the first reference list is a list MR. TISI: Correct. 4 of papers that I actually cited in the text of 4 MR. KLATT: -- that you're referring <sup>5</sup> the report, and then I had -- any papers that I to? <sup>6</sup> reviewed or other data that I reviewed, I kept in MR. TISI: Correct. 6 MR. KLATT: And they have binders in <sup>7</sup> folders on my computer. Unfortunately, I had two hard drives them? <sup>9</sup> malfunction while I was in the process of writing MR. TISI: They have binders in them. 10 this report. Luckily, I backed up most of it, so <sup>10</sup> And I haven't even looked at them because they 11 it's possible a few things didn't get documented, <sup>11</sup> were sent out from the Ashcraft office, but my 12 ultimately, but I really tried my best to make it 12 understanding -- and you can crack them open at 13 complete and accurate, and that's why you got break -- but my understanding is there are copies <sup>14</sup> another list yesterday. of those. I don't know how many. So it's four 15 boxes, but there are duplicates in there. Q. Okay. And, I'm sorry, we forgot to mark some of these. 16 But they are -- if I understand -- and 17 And so can you tell me -- this is something I can correct them on a break -- if I understand 18 you brought with you today? them, they are copies of the references. We did 19 A. Yes. not make copies -- or they did not make copies of the materials that were considered but not 20 MR. TISI: Can I -- and he's defending the deposition; I just have a little more referenced in the reports. knowledge of the documents and how they -- at 22 Do you follow what I'm saying? 23 MR. KLATT: Yeah. What I want to least I think I do. 24 I think that in the boxes here are the 24 clarify is the four boxes here have not been in <sup>25</sup> references cited. The materials considered, I <sup>25</sup> Dr. Kane's possession, so there's no notations, Page 51 Page 53 <sup>1</sup> don't think we printed out. I don't think those <sup>1</sup> highlighting, stickies --<sup>2</sup> are in the boxes. And so I don't want there to MR. TISI: Oh, no. <sup>3</sup> be any -- there are documents she reviewed that MR. KLATT: -- that she -- that <sup>4</sup> are not here that are not referenced, but were <sup>4</sup> Dr. Kane herself would have put on what's in the identified in that list. 5 boxes --6 Does that make sense? MR. TISI: No. Those were print---7 MS. AHERN: Maybe. I'm going to go MR. KLATT: -- is that correct? through the various reference lists with her --MR. TISI: Correct. Those were printed 9 out by the plaintiffs' steering committee. MR. TISI: Okay. 10 MS. AHERN: -- and we can kind of Basically, we took her reference list and printed clarify as we go. them out for you all. There's no -- there are no 12 MR. TISI: Like, for example, I mean, I notes from her or anything like that. 13 13 just -- I'm just using an example -- we What I don't think we printed out for <sup>14</sup> supplemented with some Health Canada materials. you would be the extensive documents that she <sup>15</sup> I don't know if she brought those with her, <sup>15</sup> reviewed, including the supplemental materials <sup>16</sup> because they were not in the original report. 16 that were identified, and then put them -- we can 17 They weren't available at the time, so they would provide those in a -- you know, on a thumb drive 18 not be in the reference materials that are in the <sup>18</sup> if you want to. It's just in these depositions <sup>19</sup> binders. <sup>19</sup> we've had so far, half the time the boxes aren't 20 I know you haven't cracked open the even opened, and we didn't want to just create 21 boxes, but I don't want there to be any paper for the purpose of creating paper. But if 22 misimpression. So in terms of what they are, you you want, we can pull those for you and put them

23

in a Dropbox or whatever.

I don't want to waste your time,

<sup>25</sup> because I do want there to be -- because she

<sup>25</sup> her. Do you know what I'm saying?

23 can certainly ask her, but she may not know what

24 is in the boxes, because we printed them out for

- <sup>1</sup> doesn't necessarily know what was printed out for <sup>2</sup> her.
- 3 MS. AHERN: Understood. So let's --
- 4 MR. TISI: I'm sorry if I --
- 5 MS. AHERN: That's okay.
- 6 MR. TISI: -- took up time.
- 7 (Excerpt from Blaustein's Second
- 8 marked Exhibit 8.)
- BY MS. AHERN:
- Q. Doctor, I'm handing you what's been <sup>11</sup> marked as Exhibit 8 to your deposition.
- 12 A. Yes.
- 13 Q. Is this something that you brought with
- 14 you today in response to the Notice of
- 15 Deposition?
- 16 A. It's something I brought because I
- <sup>17</sup> reviewed it a couple days ago. It probably falls
- <sup>18</sup> within the deposition. I know you wanted to see
- <sup>19</sup> everything that I reviewed.
- 20 Q. So, first of all, tell me what this is.
- 21 What is Exhibit 8?
- 22 A. This is a page from Blaustein's second
- <sup>23</sup> edition of the Pathology of the Female Genital
- <sup>24</sup> Tract.
- 25 Q. Do you know what page it is?

- Page 56 Q. And, Doctor, the additional materials
- <sup>2</sup> to -- of Dr. Sarah Kane that were provided to us
- <sup>3</sup> yesterday, you list "Kurman defense report" from
- <sup>4</sup> a case by the name of Ristesund.
- Did you not receive that?
  - A. I asked for -- yeah, I did receive
- that.
- Q. You received it?
- MR. ROTMAN: What she -- what she was
- saying is she --
- 11 MS. AHERN: Wait. I'm asking her the <sup>12</sup> question.
- Q. Did you receive the report, the Kurman defense report, from a case by the name of
- 16 A. Yes. I had requested a defense report written by Kurman, if they had anything, and that
- is what I received.
- 19 Q. Okay. I thought just a minute ago you
- said you had not received one because it wasn't available to you.
- 22 A. I'm talking about the MDL, the curr---
- 23 Q. Ah.
- 24 A. -- the current defense expert witness
- 25 reports.

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- A. Unfortunately, it is cut off. This --
- <sup>2</sup> I don't have this textbook. I found this, I
- <sup>3</sup> think, on Google Books, actually.
- Q. And so why are you bringing it today
- 5 again?
- A. Because I reviewed it.
- Q. Okay. And why did you review this?
- A. Well, I recently became aware that
- <sup>9</sup> Dr. Kurman is a medical expert witness for the
- <sup>10</sup> defense, so I was more curious. I actually asked
- 11 the plaintiffs' attorneys for a report -- any
- 12 report that Dr. Kurman had done, because I was
- 13 trying to understand his -- what his viewpoint
- 14 might be. I don't have his defense report
- <sup>15</sup> because they're not available to us yet, but I
- <sup>16</sup> was trying to get a sense for what defense
- <sup>17</sup> medical experts -- their viewpoints.
- And so I did a search for, basically, "talc"
- <sup>19</sup> and "Kurman" and I found this (indicating). And
- 20 then I have two other editions, so I looked
- 21 through my other editions for any references to
- <sup>22</sup> talc. Because Kurman edited the fourth and fifth
- <sup>23</sup> edition. I do not believe he edited the second
- <sup>24</sup> edition, which is -- this one page is from
- <sup>25</sup> (indicating).

- Q. Okay.
- A. Yeah.
- Q. Thank you for the clarification.
- So you have seen at least one defense report

- that was written by Dr. Bob Kurman; right?
- A. Yes.
- Q. And did you -- do you know Dr. Robert
- Kurman, either personally or by reputation?
- A. By reputation and I've gone to dinner
- 10 with him before, but I don't know him well.
- 11 Q. And what do you know about Dr. Kurman?
- 12 A. So he is a well-known gynecologic
- pathologist out of -- he was out of Johns
- Hopkins. I believe he recently retired.
- But he certainly edited one of the main
- gynecologic pathology textbooks and was -- you
- know, published quite a bit in gynecologic
- pathology, so his name is well known in our community. 19
- Q. And you've actually cited to a number 21 of his papers in your report; correct?
- 22 A. Yes, I'm sure I have. I know at least
- 23 one or two. 24 Q. And Dr. Kurman was a Robert Scully
- <sup>25</sup> fellow, as well, wasn't he?

A. I actually don't remember if he trained under Scully. It's possible. I don't remember whether or not he did.

Q. Okay. This Exhibit 8 that you brought with you today, are you bringing it here because it mentions granulomatous endometritis caused by foreign bodies?

8 A. It says, "Talc may be introduced into
9 the endometrial cavity by instruments
10 contaminated with talcum powder or by gloves
11 during a pelvic examination. Patients may be

asymptomatic or may present with menorrhagia.
 Microscopically, the extent of the granulomatous

14 inflammatory reaction depends on the quantity of

 $^{15}$  the talc inoculated. The infiltrate is

<sup>16</sup> characterized by histiocytes and foreign-body

17 multinucleated giant cells surrounded --

 $^{18}\,$  surrounding the talc crystals, along with

 $^{19}\,$  lymphocytes and plasma cells. The crystals

 $^{20}\,$  appear as refractile, birefringent, needle-like,

or fan-shaped splinters in polarizing light."
 Q. Are you familiar with the type of

<sup>23</sup> reactions -- tissue reactions that are elicited

24 by talc in tissue?

A. I know -- I'm aware that you can get

A. I'm not really sure what you mean by

<sup>2</sup> "types." You mean foreign body versus infectious

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<sup>3</sup> versus --

Q. Yes.

A. Those would be the top of the list.

Q. And are there subtypes of granulomatous

<sup>7</sup> inflammation within those categories?

A. Well, you can have multinucleated giant

<sup>9</sup> cells that aren't part of a granuloma.

You can see -- another common situation where you'll see granulomas is in Crohn's

12 disease. That's granulomatous inflammation in

the colon due to inflammatory bowel disease.

And I think -- yeah. So foreign body and infection are -- and certain diseases that may

<sup>16</sup> cause granulomatous -- that's sort of the

<sup>17</sup> hallmark of that type of disease, sarcoidosis.

Q. Have you ever -- the Figure 12.6 in Exhibit 8 actually doesn't have anything to do

with granulomatous endometritis, does it?

A. No. That figure is of a type of

<sup>22</sup> finding you can see in the endometrium that's not

<sup>23</sup> a granulomatous reaction.

Q. And how did Exhibit 8, if it does,

<sup>25</sup> inform your opinions in this case?

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<sup>1</sup> granulomous -- granulomatous inflammation, like

<sup>2</sup> here, and you can have acute inflammation, for

<sup>3</sup> example, in pleurodesis and chronic inflammation,

<sup>4</sup> like lymphocytes and plasma cells.

Q. Are you an expert in granulomatousinflammation?

A. Well, I certainly am familiar with the -- with diagnosis of granulomatous inflammation. I see it quite commonly.

Q. Under what circumstances do you commonly see granulomatous inflammation?

12 A. You see it often in -- the most common 13 situation would be foreign-body giant cell. That

<sup>14</sup> could be due to foreign bodies or it could be due

to -- a common situation we might see them is
 what's called an epidermal inclusion cyst in the

skin, and you actually can get a granulomatous

18 response to keratin that has -- if it's ruptured

and gone into the dermis, you can see that.
 Infections is another one. In tuberculosis,

you can see granulomatous inflammation. Fungal

<sup>22</sup> infections, you can see granulomatous

<sup>23</sup> inflammation.

Q. How many different types of granulomatous reactions are there?

r age 37

21

A. Well, it was just a piece of

<sup>2</sup> information I found, again because I was curious

3 mostly about what Kurman's opinion might be on

<sup>4</sup> this litigation. So...

<sup>5</sup> Q. Does -- do you know what -- did this

6 come from a particular chapter in Blaustein's second edition?

A. This, I don't -- I have no more

<sup>9</sup> information on this particular one. Um --

Q. Do you know who authored the chapter?

MR. ROTMAN: Excuse me. I think she was in the middle of an answer.

Q. I didn't mean to cut you off. Please quality go ahead.

A. Again, I don't have any more information. I brought it because I saw it.

Q. Okay. So you don't know who authored the chapter that contains this information in

<sup>19</sup> Exhibit 8?

20

A. Not for this edition, I do not.

Q. And are you -- do you -- did you say earlier you weren't sure if Dr. Kurman edited

<sup>23</sup> this particular version of Blaustein's Pathology?

A. I don't believe he did. I know he edited the fourth and fifth, but I don't believe

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- <sup>1</sup> he did the second.
- Q. Does the information in Exhibit 8
- <sup>3</sup> inform your decisions regarding talc and
- <sup>4</sup> causation with regard to ovarian cancer?
- <sup>5</sup> MR. ROTMAN: Objection.
- <sup>6</sup> A. It's another piece of evidence. It
- <sup>7</sup> mentions granulomatous inflammation due to talc
- 8 in the endometrium.
- <sup>9</sup> Q. And what does that have to do with <sup>10</sup> ovarian cancer?
- A. Well, one of the plausible biologic
- $^{12}\,$  mechanisms for talc causing ovarian cancer is
- <sup>13</sup> that it elicits a chronic inflammatory reaction.
- Q. And there are different types of
- <sup>15</sup> chronic inflammatory reactions, aren't there?
- A. Yes, there are.
- Q. Is a foreign-body reaction the same as
- 18 the type of inflammation seen, for instance, in
- <sup>19</sup> ulcerative colitis? If you know.
- A. No, I'm just rereading the question.
- Ulcerative colitis, you don't typically see
- <sup>22</sup> foreign-body reaction.
- Q. Ulcerative colitis is one of the
- <sup>24</sup> conditions that has been associated with the
- <sup>25</sup> development of cancer; correct?

- 1 going to --
- MS. AHERN: One second, please.
- <sup>3</sup> Q. You can see inflammatory conditions
- <sup>4</sup> that are not in any way linked to the development
- <sup>5</sup> of cancer; correct?
- A. So not all chronic inflammation is
- <sup>7</sup> going to lead to cancer, but chronic inflammation
- 8 is a well-established cause of different types of
- <sup>9</sup> cancer.
- MR. ROTMAN: I'd like to take a break.
- 11 We've been going a little over an hour.
  - MS. AHERN: Okay.
- THE VIDEOGRAPHER: Here ends Media 1.
- 14 Off the record, 10:21 a.m.
  - (A recess was taken.)
- 16 THE VIDEOGRAPHER: Here begins Media
- <sup>17</sup> No. 2 in today's deposition of Sarah Kane, M.D.
- 18 Back on the record, 10:37 a.m.
- 19 BY MS. AHERN:
- Q. All right. Dr. Kane, we were -- we
- 21 left off, we were talking about chronic
- 22 inflammation and cancer.
- Do you remember that?
- 24 A. Yes.
- Q. Okay. Can you identify for me the

- A. Those with ulcerative colitis have an
- <sup>2</sup> increased risk of colon cancer, yes.
- Q. Do you know of any particular cancers
- <sup>4</sup> that have been linked to foreign-body responses?
  - A. Well, foreign-body responses -- for
- 6 example, asbestos is known to cause an
- <sup>7</sup> inflammatory response and asbestos is known to
- 8 cause mesothelioma and lung cancer, and the IARC
- <sup>9</sup> states that it causes ovarian cancer.
- Q. And how is the response to asbestos
- 11 different from the response that's been
- 12 documented with talc in terms of tissue reaction?
- A. So you can see a granulomatous reaction
- 14 to talc. You can see an acute reaction to talc
- <sup>15</sup> in pleurodesis patients.
- This page here mentions plasma cells and
- 17 lymphocytes, which you do see in Crohn's disease.
- Q. You see plasma cells and lymphocytes in
- <sup>19</sup> a number of different inflammatory conditions;
- 20 correct?
- MR. ROTMAN: You can answer.
- A. Yes, you can see lymphocytes and plasma
- <sup>23</sup> cells in inflammatory conditions.
- Q. And you can see inflammatory con---
- MR. ROTMAN: Object -- Object -- I was

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- 1 types of ovarian cancer that have been associated
- <sup>2</sup> with chronic inflammation?
- A. So we know that endometriosis, as an
- <sup>4</sup> example, causes an inflammatory response. The
- <sup>5</sup> types of ovarian cancer that are associated with
- <sup>6</sup> endometriosis are clear cell carcinoma and
- endometrioid carcinoma.
- 8 Q. Are there other forms of ovarian cancer
- <sup>9</sup> that are associated in the literature with
- 10 chronic inflammation?
- 11 A. So we do see chronic inflammation
- 12 within other types of ovarian cancer, so
- high-grade invasive serous, low-grade serous
- carcinoma, you do see chronic inflammation within
- those tumors.
- Q. Let me be more precise, because it's
- sort of a chicken and the egg kind of thing.
- 18 I'm asking what sort of inflammatory
- 19 conditions have been associated with the
- <sup>20</sup> development or the cause of ovarian cancers?
- A. Yeah. So the mechanisms of a lot of
- ovarian cancer have been somewhat elusive.
- Unfortunately, it's a rare disease. It's hard to
- study. It's difficult to have sort of a large
- enough cohort to really get good data on ovarian

9

cancer, and so we don't really know all of the
 mechanisms of the initiation of ovarian cancer.

But we know that chronic inflammation, we
see it in ovarian tumors. We know that -- and
putting it in a talc perspective, we know that
talc can cause chronic inflammation and so -- and
we know that chronic inflammation causes other

types of cancer.
 Q. So is that -- can you name any other
 types of ovarian cancers that have been
 associated in the literature with chronic
 inflammation in terms of a specific etiology for
 that cancer?

A. So, again, I would say I don't know if
we can say for certain what the specific etiology
is for all types of surface epithelial cancer,
but we do know that, again, clear cell has been
associated with endometriosis, which causes
chronic inflammation, and we see chronic
inflammation in tumors. But the mechanisms for
these types of tumors have not been completely
mechan--- elucidated.

Q. So do you not know of any other specific ovarian tumors that have been associated in the literature causally with chronic <sup>1</sup> inflammation, yes.

Q. And you would agree that many, if not most, cancers are somewhat proinflammatory.

A. I think tumors can be -- can be proinflammatory, yes.

Q. So the tumor itself can invoke an
 inflammatory response during its development;
 correct?

A. Some tumors will.

Q. And often the tumors will hijack portions of the immune system to help them to grow and metastasize; correct?

A. I'm not sure exactly what you mean by "hijack," but there are mechanisms to -- or literature to suggest that.

Q. So just looking at a high-grade serous carcinoma and seeing inflammation doesn't tell you anything about whether that inflammation caused the tumor or whether it was caused by the tumor; is that correct?

A. So, again, the mechanisms are not that clear, so we don't know for sure. But is all chronic inflammation seen in a tumor the cause of the tumor? I don't know if we know the answer, but, you know, it's definitely an associated

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Page o

<sup>1</sup> inflammation?

A. Again, I don't believe that the
 mechanisms of all of these tumors have been
 elucidated completely.

Q. And I do understand your answer, but I just want to know if there are -- if you're aware followed inflammation with other types of ovarian cancer other than the two that you've mentioned, endometrioid and clear cell carcinoma.

A. Well, again, I mentioned that in serous tumors, we do see chronic inflammation in those tumors.

And with smoking and mucinous ovarian
cancers, you know, it's been -- there's some
literature that suggests, you know, smoking is
associated with mucinous and those -- that can
cause inflammatory reactions.

But, again, this is all -- it's not entirely clear what the etiology of some of these tumors are.

Q. You mentioned that in high-grade serous carcinoma, you see associated inflammation; correct?

A. You can see associated chronic

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<sup>1</sup> pattern that we see with ovarian tumors.

Q. So my question is a little different,
if I can go back and find it. And it's missing.

My question is: As a pathologist looking at
 slides from a particular patient who has ovarian
 cancer --

A. Mm-hmm.

Q. -- just the observation that there is inflammatory cells associated with that tumor doesn't tell you anything, as a pathologist, in terms of whether that inflammation caused the tumor or if the tumor caused the inflammation.

A. Well, I think it depends on the situation. You know, again, for ovarian tumors, if we have a clear cell carcinoma, we could, you know, deduce, especially if you see associated endometriosis, that that is the likely cause, and, again, depending on the patient and the patient's risk factors.

But, yeah, if you're looking just at one slide without any other information, it would be difficult to say.

Q. Well, you would never just be looking at an one slide, would you? You'd be looking at all of the slides that were available for a

<sup>1</sup> particular patient, which would include

- <sup>2</sup> diagnostic tissue or tumor tissue, as well as
- <sup>3</sup> normal, nontumor tissue; correct?
- A. Right.
- <sup>5</sup> Q. Okay. So you would never be in a
- <sup>6</sup> situation where you're just looking at a single
- slide and making a determination, unless it's
- 8 maybe cytology or a biopsy; correct?
  - A. I'm sorry. I'm just looking at the --
  - Q. Sure.

9

10

21

- A. I'm not sure what the -- the first
- <sup>12</sup> question came out kind of funny.
- Q. What I was saying is there would never
- be a situation where you're only looking at a
- <sup>15</sup> single slide to make a diagnostic determination
- <sup>16</sup> unless it was from a biopsy sample or a cytology.
- A. That's what I was going to kind of
- 18 rewind and clarify, that sometimes there is only
- 19 one slide. So --
- Q. Is that an accurate statement?
  - MR. ROTMAN: Let her finish the answer.
- <sup>22</sup> I think she was saying "so" and then you asked
- <sup>23</sup> another question.
  - A. So in a larger specimen type, it's
- <sup>25</sup> correct you would be looking, usually, at more

- MS. AHERN: I'm not finished with my
- <sup>2</sup> question. You can object when I'm done with my
- <sup>3</sup> question.
- MR. ROTMAN: I object to you asking a question --
- 6 MR. KLATT: She didn't have --
  - MR. ROTMAN: -- when she's asking --
- 8 MS. AHERN: I can ask a question
- <sup>9</sup> whenever I want. She doesn't have to answer the
- 10 question if you instruct her not to, but while
- 11 she's spending time looking through her report,
- 12 I'm going to ask her a different question based
- on her recollection.
- MR. ROTMAN: Well, you've asked her a
- <sup>15</sup> question, she's in the process of answering it,
- <sup>16</sup> and you're asking -- you're asking her a second
- <sup>17</sup> question. That's what I'm objecting to.
- 18 BY MS. AHERN:
- 19 O. Doctor --
- MR. ROTMAN: Let her finish --
- Q. -- can you answer the question without
- 22 looking at your report?
- A. Well, I'd like to refer to my report if
  - <sup>4</sup> you're asking questions.
- <sup>5</sup> Q. And that's fine. My only question,

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- <sup>1</sup> slide if there's more tissue that would fit in
- <sup>2</sup> one cassette to make one slide.
- <sup>3</sup> Q. Let's talk about high-grade serous
- <sup>4</sup> carcinoma.
  - High-grade serous carcinoma is the most
- <sup>6</sup> common form of ovarian cancer; correct?
  - A. It's most -- yes.
- 8 Q. By far the most common form of ovarian
- <sup>9</sup> cancer; is that also correct?
- A. It's the most common form, yes.
- Q. So let's talk about high-grade serous
- <sup>12</sup> carcinoma in the context of chronic inflammation.
- Do you know of any published literature that
- <sup>14</sup> connects chronic inflammation causally with the
- <sup>15</sup> development of high-grade serous carcinoma?
- A. I can -- in my report, I actually do
- <sup>17</sup> have a section. Let me find it.
  - 8 MR. ROTMAN: It might be easier to take
- 19 off the clip, if that helps you flip the pages,
- <sup>20</sup> because it's two-sided.
- Q. Doctor, while you look for that, just
- 22 to the best of your recollection, do you remember
- reading any studies that concluded that --
- MR. ROTMAN: I object. She's in the
- <sup>25</sup> middle of answering --

- 1 really, was, just based on your recollection as
- <sup>2</sup> we sit here discussing chronic inflammation and

- <sup>3</sup> ovarian cancer, if you are aware of studies that
- 4 causally associate chronic inflammation with
- <sup>5</sup> high-grade serous carcinoma?
- 6 A. So there's definitely literature that
- 7 has looked at associations between chronic
- 8 inflammation and the resulting sort of
- 9 expressions.
- And that's what -- I was trying to point you
- 11 to my report on Page 12, the end of it, where it
- 12 says, "There also is evidence that talc induces
- 13 macrophage TNF alpha expression and macrophages
- that express TNF alpha promote ovarian tumor
- genesis. TNF alpha is involved in chronic
- 16 inflammation and induces mutations in vitro and
- 17 TNF alpha-induced chromosomal mutations occur
- 18 mostly in cells with P53 aberrations and, of
- 19 note, high-grade serous carcinomas typically have
- 20 inactivating mutations in P53."
- So, again, we don't know all the mechanisms
- of all of these tumors, but there's certainly
- 23 literature that is investigating those types of
- 24 associations.
- MR. KLATT: Object. Nonresponsive.

Page 74 MS. AHERN: Same.

- Q. But since you brought it up, on Page 12
- $^{3}$  of your report, can you translate for me that
- <sup>4</sup> paragraph that you just read and put it in lay
- 5 terms and explain how that has anything to do
- 6 with causal associations with ovarian cancer and
- 7 chronic inflammation caused by tale?
- MR. ROTMAN: Objection.
- 9 A. Well, I think it's there in the report.
- 10 If talc is inducing macrophage TNF alpha
- 11 expression and macrophages that express TNF alpha
- 12 can promote ovarian tumor genesis that occur
- 13 mostly in the -- TNF alpha-induced chromosomal
- 14 mutations occur mostly in cells with P53
- <sup>15</sup> aberrations, I think that's relevant in looking
- <sup>16</sup> at evidence that -- for a plausible mechanism
- <sup>17</sup> that inflammation caused by talc can cause
- 18 aberrations in -- can cause P53 aberrations. And
- 19 we know that high-grade serous carcinomas, many
- 20 of them have P53 mutations.
- Q. And high-grade serous carcinomas with
- 22 P53 mutations, what causes the P53 mutations?
- A. Well, again, the literature is still
- 24 evolving into all of the mechanisms regarding
- 25 this. Some of them we know are sort of aberrant

<sup>1</sup> genomic event in the development of high-grade

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- <sup>2</sup> serous carcinoma?
- <sup>3</sup> A. So, again, I don't know if I -- I don't
- 4 know if we always know what the earliest
- <sup>5</sup> identifiable genomic event in the development of
- <sup>6</sup> high-grade serous carcinoma is.
- Q. Have you reviewed the literature on
- 8 high-grade serous carcinoma from a molecular
- <sup>9</sup> genetics perspective?
- A. Yes, I reviewed papers on molecular genetics, yes.
- Q. Do those papers indicate that one of
- 13 the earliest, if not the earliest, genomic event
- 14 in the development of high-grade serous carcinoma
- 5 that has been identified are mutations in P53?
- A. So, again, you can see P53 mutations,
- <sup>17</sup> for example, in the fallopian tubes and you can
- have sort of serous tubal intraepithelial
- <sup>19</sup> carcinomas in the fallopian tube, which are
- thought to be early precursors for high-gradecarcinoma.
- Q. High-grade serous carcinoma?
- A. Mm-hmm. Sorry, high-grade serous
- 24 carcinoma.
  - Q. And do you agree that the STIC lesions

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- <sup>1</sup> mutations, and we don't always know why they
- <sup>2</sup> occur.

1

- We know that women with BRCA1 and BRCA2
- 4 mutations have -- can get high-grade -- have a
- <sup>5</sup> higher risk of high-grade serous carcinoma.
- 6 But, again, I don't think we know all of the
- <sup>7</sup> mechanisms that cause, you know, all of these
- 8 tumors.
- 9 MS. AHERN: Objection. Nonresponsive.
- Q. Doctor, do you know, as we sit here
- today, what causes P53 mutations in high-grade
- 12 serous carcinoma?
- A. I think I answered that. We know, I
- 14 mean, what's in my report and women with BRCA1
- <sup>15</sup> and BRCA2 mutations. But, again, the literature
- 16 is evolving with this.
- Q. Doctor, are you suggesting that BRCA1
- <sup>18</sup> and -2 mutations cause P53 mutations in
- 19 high-grade serous carcinomas?
- A. What I'm saying is that we know that
- 21 BRCA1 and BRCA2 mutation patients have a high
- <sup>22</sup> risk of ovarian cancer.

- And so you're asking me what causes, so, you
- <sup>24</sup> know, I'm telling you the data that we have.
  - Q. What is the earliest identifiable

- <sup>1</sup> or serous tubal epithelial carcinomas in the
- <sup>2</sup> fallopian tubes are currently known to be the
- <sup>3</sup> earliest manifestation of high-grade serous
- 4 carcinoma?
- A. Well, it depends on what you mean by
- 6 "manifestation." I mean, it takes a period of
- <sup>7</sup> time from initial insult until we can recognize
- 8 something histologically as a precursor to
- <sup>9</sup> cancer.
- Q. That was -- you're right, that was a
- <sup>11</sup> bad question.
- Do you recognize serous tubal
- 13 intraepithelial carcinomas as an in situ serous
- 4 carcinoma?
- A. I think evidence is supportive of
- <sup>16</sup> serous tubal intraepithelial carcinomas being a
- <sup>17</sup> precursor to some high-grade serous carcinomas.
- Q. And when you say "precursor," do you
- <sup>9</sup> mean a frank cancer or a premalignant lesion?
- What do you mean by "precursor"?
- A. Well, again, not -- we don't know if
- <sup>22</sup> all STICs are going to become high-grade serous
- carcinomas. STICs were originally discovered in
- <sup>24</sup> looking at fallopian tubes of BRCA1 and BRCA2
- patients that had -- what's the word I'm looking

- <sup>1</sup> for? -- prophylactic salpingectomies to decrease <sup>2</sup> their risk of ovarian cancer.
- And that was -- you know, they had evaluated
- 4 these precursor lesions, and so the thought is
- <sup>5</sup> that when you have these atypical cells in the
- 6 fallopian tube fimbria that are -- that have P53
- aberrations, that that -- the belief is that
- 8 that's a precursor to some of the serous invasive
- carcinomas that we see.
- 10 Q. Do you consider STIC lesions to be 11 carcinomas?
- 12 A. They're -- the name is intraepithelial 13 carcinoma, so its analogous term would be sort of <sup>14</sup> an in situ cancer.
- 15 Q. It is a cancer; correct?
- 16 A. Well, they're calling them
- <sup>17</sup> intraepithelial carcinomas because they have -- I
- mean, it's sort of semantics. They have a P53
- mutation and they're recognizable histologically.
- 20 Q. Do you agree that they're carcinomas or 21 cancer?
- 22 A. I certainly agree that they can be
- <sup>23</sup> precursors to invasive serous carcinomas. It's
- 24 sort of semantics, precursor -- it -- it's --
- 25 it's sort of the same question as ductal

- Page 80
- <sup>1</sup> that ovulation event, you might end up with <sup>2</sup> precursors.
- We don't really have a model in a lot of
- <sup>4</sup> ovarian cancers where you can follow a precursor
- <sup>5</sup> all the way through to -- what we think is a
- <sup>6</sup> precursor all the way through to the final tumor.
- <sup>7</sup> We just -- we don't really have a lot of data on
- those in-between steps.
- So it was very, very interesting when they
- discovered these STIC lesions in the fallopian
- tube fimbria that had P53 mutations. It was
- pretty compelling that these might be the
- precursor lesions to serous -- high-grade serous
- carcinomas.
- 15 Now, are all high-grade serous carcinomas
- <sup>16</sup> caused by STIC lesions or are they all -- is a
- 17 STIC lesion a precursor to all serous --
- 18 high-grade serous carcinomas? I don't think we
- 19 know that.
- Q. Do you know of any data associating
- <sup>21</sup> high -- excuse me, associating chronic
- inflammation or injury with the development of
- STIC lesions?
- A. So, again, I think the literature is
- still evolving with this -- these STIC lesions.

- <sup>1</sup> carcinoma in situ in the breast. There's
- <sup>2</sup> literature that debate about is ductal carcinoma
- <sup>3</sup> in situ a true cancer or is it a risk factor for
- <sup>4</sup> cancer, and what is the meaning of treatment for
- <sup>5</sup> DCIS in the breast? And I would say that that's
- <sup>6</sup> sort of analogous to STIC lesions in the
- <sup>7</sup> fallopian tube.
- Q. Okay. Do you agree that most
- <sup>9</sup> high-grade serous carcinomas arise from the
- <sup>10</sup> endometrial cells in the fallopian tube?
- 11 A. High-grade --
- Q. Epithelial cells in the fallopian tube. 12
- <sup>13</sup> Excuse me.
- A. So, again, we -- this was something
- 15 that the medical community really struggled with,
- 16 trying to find the precursor lesions to a lot of
- <sup>17</sup> these tumors.
- 18 And for a lot of years it was thought that
- 19 maybe serous carcinomas derived from what are
- <sup>20</sup> called epithelial inclusion cysts, so, basically,
- 21 the thought was that during ovulation, you're
- <sup>22</sup> disrupting the surface epithelium of the ovary
- <sup>23</sup> and when the ovary sort of heals itself, you get
- 24 this invaginated epithelium within the ovary and
- 25 that maybe because of inflammatory response to

Q. Sorry. Were you finished? I don't

- <sup>2</sup> want to interrupt you if you're thinking.
  - A. No, I'm thinking.
- Again, I don't think we really have the data
- on where these STIC lesions are coming from.
- Q. As part of your literature review for
- your MDL report, did you search specifically for
- papers that might be linking or associating
- chronic inflammation with early precursor lesions
- to serous invasive carcinomas or high-grade
- 11 serous carcinomas?
- 12 A. I was certainly looking for literature
- with the association of inflammation with ovarian cancer.
- 15 Q. With -- did you look specifically at <sup>16</sup> the various subtypes of ovarian cancer?
- 17 A. Yes.
- 18 Q. Is there a particular subtype of
- ovarian cancer that you think is associated with 20 talc use?
- A. So most of the epidemiology literature
- show the highest association with high-grade 23
- serous invasive carcinoma.
- 24 Q. When you say "highest association," are
- <sup>25</sup> you talking about strength of association?

- 1 A. I'm talking about the -- for example,
- <sup>2</sup> on the cohort studies, they found an association
- <sup>3</sup> with high-grade serous carcinoma.
- 4 And in a lot of the case-control studies,
- <sup>5</sup> when they looked at tumor subtype, a lot of those
- 6 tumors were serous carcinomas. Now, some of them
- <sup>7</sup> broke them out by relative risk by subtype; some
- 8 of them didn't. I'd have to look at the papers.
  - Q. Do you remember which cohort study
- 10 found an association with high-grade serous
- 11 carcinoma?
- A. I believe the Nurses' Health Study.
- 13 I'd have to look at it to see the numbers.
- Q. Was there more than one cohort study
- 15 that you recall associated talc use with
- <sup>16</sup> high-grade serous carcinoma?
- A. I'd have to look at them just to be
- 18 sure, but the one that I remember is the Nurses'
- 19 Health Study.
- Q. Are there any other subtypes,
- 21 histologic types, of ovarian cancer that you
- 22 believe are associated with talc use?
- A. Well. I think talc use -- I think talc
- 24 use could be associated with the -- any type of
- <sup>25</sup> surface epithelial cancer. That seems to bear

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- <sup>1</sup> out in the epi data. They've certainly seen an
- <sup>2</sup> association with different types of surface
- <sup>3</sup> epithelial cancers in the epi data, the strongest
- <sup>4</sup> association being with the serous invasive.
- Q. Have you seen any data supporting an
   association with talc use and a low-grade serous
- <sup>7</sup> carcinoma?
- 8 A. I'd have -- again, I'd have to look at
- <sup>9</sup> the different studies to break it out, but I know
- there was a study that found an increased risk
- there was a study that round an increased risk
- $^{11}$  with serous borderline carcinomas. I'd have to
- 12 look through the individual data sets.
  - Q. And serous borderline -- are -- serous
- <sup>14</sup> borderline tumors are not carcinomas; correct?
- <sup>15</sup> A. Sorry. I -- serous borderline tumors,
- <sup>16</sup> yes. I misspoke.
- Q. And you don't remember what study that
- <sup>18</sup> was that associated talc use with serous
- <sup>19</sup> borderline tumors?
- A. I would have to look at the data -- or
- <sup>21</sup> the study.
- Q. So do your opinions in this case apply
- <sup>23</sup> equally to all histologic subtypes of ovarian
- <sup>24</sup> cancer or are there specific subtype or subtypes
- 25 that you are opining are caused by talc?

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- A. So I think the most consistent finding
- <sup>2</sup> is with high-grade serous carcinoma, but there's
- <sup>3</sup> data for the other types of surface epithelial
- <sup>4</sup> carcinomas.
- <sup>5</sup> Q. And what are the surface types of
- 6 carcinomas?
- A. So they're endometrioid and clear cell,
- <sup>8</sup> and mucinous less so than, I believe, the
- <sup>9</sup> endometrioid and clear cell, although I believe,
- again, in the 2010 Nurses' Health -- is that --
- <sup>11</sup> I'd have to go back -- I -- there was a mention
- of mucinous -- I'm not absolutely sure it was the
- 13 Gates 2010, but there was a mention of an
- 14 increased risk of mucinous in one of those
- increased risk of mucinous in one of those
- 15 studies.
- Q. Do you agree that the different
- <sup>17</sup> histologic subtypes of epithelial ovarian cancer
- <sup>8</sup> are likely to have different genetic causes?
- A. I know they're associated with
- <sup>20</sup> different genetic mutations.
- Q. Do they develop along distinct
- <sup>22</sup> molecular genetic pathways?
- A. That's what the literature suggests at
- this point.
  - Q. Do they behave differently?

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- A. So the high-grade surface epithelial
- <sup>2</sup> carcinomas have a more aggressive pathway or
- <sup>3</sup> presentation. The low-grade surface endothelial
- 4 carcinomas tend to have a more indolent
- progression.

13

- Q. You've used the term "surface
- <sup>7</sup> epithelial carcinomas" and I haven't seen that
- 8 term generally used in the literature.
- 9 When you talk about surface epithelial
- carcinomas, are you talking about serous or are
- 11 you talking about endometrioid or are you talking
- 12 about clear cell? Mucinous?
  - A. Epithelial carcinomas.
- 4 Q. That would encompass all of those,
- wouldn't it? Wouldn't surface epithelial
- <sup>16</sup> carcinomas encompass mucinous, clear cell,
- endometrioid, and serous subtypes? They're all
- 18 epithelial ovarian cancers; correct?
- A. Yes. That's what I'm referring to when
- <sup>20</sup> I -- because we also have germ cell tumors and
- stromal tumors of the ovary. Those are much more
- <sup>22</sup> rare, and I'm not -- you know, I don't think
- 23 there's associations with those. So, yes, we're
- <sup>24</sup> talking about epithelial carcinomas, to be clear.
  - Q. Well, and just -- because I want to

<sup>1</sup> make sure your testimony is also clear.

- So if we could, if you could use the
- <sup>3</sup> specific subtype names, like serous or
- 4 endometriod --
- <sup>5</sup> A. Okay.
- 6 Q. -- or clear cell. That way there's no
- <sup>7</sup> confusion later on about what you intended.
- 8 So when you say -- let's see. Let me go
- <sup>9</sup> down. Sorry.
- When you say "high-grade surface epithelial"
- <sup>11</sup> carcinomas," are you talking about high-grade
- 12 serous carcinomas?
- MR. ROTMAN: Objection. You're asking
- <sup>14</sup> her to reflect back on all of her prior answers
- 15 to all of your prior questions, whether she was
- <sup>16</sup> referring to the same thing in each one?
- Q. Do you understand my question?
- A. I'd have to figure out what answer
- 19 you're talking about, but --
- Q. So you just -- just a few questions
- <sup>21</sup> ago, you answered -- I said, "Do the different
- 22 types -- histologic types develop along the same
- <sup>23</sup> molecular genetic pathways?"
- You said, "That's what the literature
- <sup>25</sup> suggests at this point."

- Does that make sense?
- <sup>2</sup> A. Okay. Yes. Okay.
- Q. Okay. All right. So let me ask my

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- <sup>4</sup> question that I asked a little while again, and
- <sup>5</sup> you tell me -- you can answer it again with the
- <sup>6</sup> terminology.
- 7 Do the different histologic subtypes of
- <sup>8</sup> ovarian cancer behave differently?
  - A. Yes. Again, the high-grade ones
- generally behave differently than the low-gradeones.
- Q. Okay. Do endometrioid and clear cell carcinomas behave differently from high-grade
- <sup>14</sup> serous carcinomas?
- A. The high-grade serous carcinomas tend to behave more aggressively.
- Q. Do low-grade serous carcinomas behave
- <sup>18</sup> differently from endometrioid, clear cell, and
- 19 high-grade serous carcinomas?
- A. They tend to be less aggressive. They
- <sup>21</sup> all tend to be less aggressive than the
- <sup>22</sup> high-grade serous carcinomas or other high-grade
- <sup>23</sup> carcinomas of the ovary.
  - Q. And are they thought to each have
- <sup>25</sup> different cells of origin?

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- I asked, "Do they behave differently?"
- 2 And then you responded, "So the high-grade
- <sup>3</sup> surface epithelial carcinomas have a more
- <sup>4</sup> aggressive pathway or presentation. The
- <sup>5</sup> low-grade surface epithelial carcinomas tend to
- 6 have a more indolent..."
- Were you talking about high-grade serous and
- 8 low-grade serous carcinomas?
- 9 A. I was talking -- sorry. I was talking
- 10 about high-grade serous carcinomas, yeah. And we
- <sup>11</sup> also have sort of undifferentiated carcinomas
- <sup>12</sup> that are also considered high grade.
- Q. Okay. And were you talking about
- 14 low-grade serous carcinomas when you said
- 15 "low-grade surface"?
  - A. No. So "surface" doesn't really refer
- 17 to cell type; it's just sort of a --
- 18 Q. Right.
- 19 A. -- an umbrella term for the epithelial
- 20 carcinoma.

- Q. Right, which is my point. I just
- 22 wanted to be clear. When you say "surface" --
- 23 A. Yes.
- Q. -- could you instead use the actual
- 25 cell type.

- A. Again, we're not entirely sure where
- <sup>2</sup> these tumors are arising from, particularly with
- <sup>3</sup> mucinous carcinomas. I think mucinous carcinomas
- <sup>4</sup> and there's also a type transitional cell, which
- <sup>5</sup> is very, very rare, and most of the literature,
- 6 when it comes to the epi data, don't really
- 7 discuss transitional cell.
- 8 But putting that aside, mucinous carcinomas
- 9 we have, I think, the least amount of data on
- where they are actually arising from. Clear cell
- 11 and endometrial carcinomas have an association
- 12 with endometriosis, but, again, you know, are all
- 13 cases of endometriod and clear cell carcinomas,
- 14 are they all arising from endometriosis? I don't
- 15 think I can say that. I don't think we know for
- 16 sure.
- And serous carcinomas, we talked about the precursor lesions and the fallopian tubes.
- So there are differences where we think the
- tumors are arising from, but, again, I don't
   think we have absolutes where we can definitively
- 22 say, you know, this particular tumor in this
- 23 particular woman arised [sic] from this precursor
- particular woman arised [sic] from this precurs or...
- Q. Okay. And do you know if the different

- histologic subtypes have been associated in the
   epidemiologic literature with different risk
- <sup>3</sup> factors?
- 4 A. Yes. Again, I think we touched on some
- <sup>5</sup> of that before. There is an association with
- <sup>6</sup> endometrioid and clear cell with endometriosis
- <sup>7</sup> and obesity.
- 8 Mucinous carcinomas have shown to be
- <sup>9</sup> associated in some studies with a smoking
- 10 history.
- High-grade serous carcinomas, it's a little
- 12 bit harder. We know that BRCA1 and BRCA2
- <sup>13</sup> patients have an increased risk.
- Q. Now that we're on that topic of
- genetics, do you know what proportion --
- <sup>16</sup> currently, what is believed to be the proportion
- of ovarian cancers that are caused by germlinemutations?
- <sup>19</sup> A. Off the top of my head, I think -- do I
- 20 have that in my report? But I -- I'm thinking
- $^{21}\,$  it's 10 to 20 percent, but that's off the top of
- 22 my head.
- Q. Have you seen any research coming out
- <sup>24</sup> of Seattle Cancer Care Alliance over the last 10
- <sup>25</sup> or 15 years that indicates the number could be as

- Q. -- this is an article by Karen
- <sup>2</sup> Malmberg, et al., entitled "Serous tubal
- <sup>3</sup> intraepithelial carcinoma, chronic fallopian tube
- <sup>4</sup> injury, and serous carcinoma development," and it

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- <sup>5</sup> was in Virchows Archives, March of 2016.
- MR. TISI: What did you mark this? I'm sorry.
- 8 MS. AHERN: I marked this one 9. Thank
- <sup>9</sup> you. No -- yes, 9.

10

- MR. TISI: Oh, I'm sorry.
- MS. AHERN: That's okay.
- Q. Do you recall if you've ever reviewed this article?
- A. It's possible. It's certainly possible
- 15 that I have seen this before in just my daily
- <sup>16</sup> practice. I don't believe I cited it in any of
- $^{\rm 17}~$  the references that I can remember, but it's
- <sup>8</sup> highly possible that I've seen it.
- Q. Do you see the first page that -- you can just skip if you want, take your time reading
- 21 it if you'd like, but the authors conclude in
- 22 their study that there is no correlation with
- <sup>23</sup> chronic tubal injury or inflammation with the
- <sup>24</sup> development of STIC lesions or the existence of
- 25 STIC lesions.

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- <sup>1</sup> high as a quarter of all ovarian cancers being
- <sup>2</sup> linked to germline mutations?
- A. That would roughly fit with what I just
- 4 said, 10 to 20 percent. I can't say for sure
- <sup>5</sup> that I have seen that. I might have. But it
- <sup>6</sup> fits with what I remember.
  - Q. I had asked you earlier if you had
- 8 reviewed any literature relating to inflammatory
- <sup>9</sup> conditions and associations with early STIC
- 10 lesions.
- And you -- and, I'm sorry, I don't want to
- 12 misstate your response. What was your response
- 13 to that?

16

- A. Had I reviewed literature? Yes, I've
- <sup>15</sup> seen literature.
  - Q. Okay.
- 17 (Article entitled "Serous tubal
- intraepithelial carcinoma, chronic
- <sup>19</sup> fallopian tube injury, and serous carcinoma
- development" marked Exhibit 9.)
- 21 BY MS. AHERN:
- Q. I'm handing you what's been marked as
- <sup>23</sup> Exhibit 9 to your deposition. And this is --
- MS. AHERN: I don't know if anyone else
- <sup>25</sup> wants one.

- Do you see that?
- A. No. Can you -- I'm sorry, can you
- <sup>3</sup> point to me --
- O. Oh, sure.
- <sup>5</sup> A. -- where?
- 6 Q. Do you see the abstract, if you carry
- <sup>7</sup> it over to the second column?
  - A. Mm-hmm. Yes.
- <sup>9</sup> Q. It says, "STIC and invasive cancer were
- seen more often in the older patients than in the
- 1 younger patients"?
  - A. Mm-hmm.
- <sup>3</sup> Q. This study is -- small study, no
- correlation with chronic tubal injury or
- <sup>15</sup> inflammation was identified.
- A. Yes, with the caveat -- that was a
- <sup>17</sup> conclusion with the caveat that it was a small
- 18 study

- Q. Have you -- as a gynecologic
- <sup>20</sup> pathologist or a pathologist who has subspecialty
- <sup>21</sup> training in gynecologic malignancies, how often
- <sup>22</sup> do you see chronic -- or evidence of chronic
- <sup>23</sup> inflammation surrounding STIC lesions?
- Or strike that. How often do you see STIC
- 25 lesions?

A. On -- certainly, I can't give you a

- <sup>2</sup> number. I've certainly made the diagnosis and
- 3 see it -- I can't give you a number of how many
  4 times
- <sup>5</sup> Q. Have you ever been involved in a study
- 6 looking specifically at STIC lesions and
- <sup>7</sup> high-grade serous carcinomas?
- 8 A. I have not been involved in a study,
- <sup>9</sup> no.
- Q. Have you ever seen evidence of chronic inflammation with a STIC lesion?
- A. Off the top of my head, I am not sure.
- 13 It's possible, but I can't really answer that off 14 the top of my head.
- Q. How often do you see chronic
- <sup>16</sup> inflammation in the fallopian tubes associated
- with high-grade serous carcinoma?
- A. You can certainly see it, but it sort
- 19 of goes along with the discussion that we had
- <sup>20</sup> before. You can see chronic inflammation within
- 21 the tumor, as well.
- And so I think, you know, the literature
- 23 is -- the research is ongoing as to, you know...
- Q. So once the tumor -- once there's a lot
- <sup>25</sup> of tumor burden in the abdominal cavity, it's
  - Page 95
- <sup>1</sup> difficult to tell where the inflammation is
- <sup>2</sup> coming from or what started it; is that correct?
- <sup>3</sup> A. Well, if there's chronic inflammation
- 4 in the tumor, it's likely the tumor has something
- <sup>5</sup> to do with the chronic inflammation.
- <sup>6</sup> But, again, you know, as we talked about
- <sup>7</sup> before, I think sometimes it is difficult to
- <sup>8</sup> tell.
- 9 MS. AHERN: Okay. Housekeeping matters
- <sup>10</sup> before I forget.
- Let me go ahead somehow and mark --
- 12 let's mark -- we can remove this later --
- 13 "Blaustein's Pathology of the Female Genital
- 14 Tract," Fourth Edition, as Exhibit 10 to your
- <sup>15</sup> deposition.
- 16 ("Blaustein's Pathology of the
- Female Genital Tract," Fourth Edition,
- marked Exhibit 10.)
- 19 BY MS. AHERN:
- Q. And, Doctor, you brought this textbook
- 21 with you today.

25

- 22 Is this your textbook?
- A. That particular copy is not. That's my
- <sup>24</sup> coworker's copy. This copy is mine (indicating).
  - Q. Okay. And inside this, you have what

- 1 looks --
- <sup>2</sup> MR. ROTMAN: Just so the record is
- <sup>3</sup> clear, when you said "this," do you want to
- 4 identify it?
- A. Sorry. The fourth edition belongs to a

Page 96

- <sup>5</sup> colleague. The fifth edition is my own.
- MS. AHERN: Okay. We'll get to that
- <sup>8</sup> one. I'll mark that next.
- <sup>9</sup> Q. There is a photocopy here, "Blaustein's
- O Pathology of the Female Genital Tract, Fourth
- <sup>11</sup> Edition," Pages 300 and -- well, Page 376,
- <sup>12</sup> Page 539, Page 540, 648, 1216, 1217, 1218.
- Is this a copy -- are these copies that you
- 14 made?

19

- <sup>15</sup> A. Yes.
- <sup>16</sup> Q. Okay.
- MR. TISI: Do you have a stapler?
- <sup>18</sup> Otherwise I'll get one.
  - MS. AHERN: No, I don't have one.
- MR. TISI: No, I'll go get one.
- 21 BY MS. AHERN:
- Q. Can you tell me why you made those
- 23 copies?
- A. I made them because it was easier than
- <sup>25</sup> lugging around a whole textbook. That's why I

- <sup>1</sup> Xeroxed them. But --
- Q. You had to bring it anyway.
- <sup>3</sup> Sorry. Go ahead.
- 4 A. But the particular pages that I copied
- <sup>5</sup> are ones that talk about granulomatous reactions
- <sup>6</sup> to talc in the female reproductive system.
  - Oh, sorry. Okay.
- 8 MS. AHERN: Okay. We'll go ahead and
- <sup>9</sup> mark those copies as Exhibit 10 to your
- deposition.And
  - Q. And just to confirm --
- MS. AHERN: Sorry. Are we on 10 or 11?
  - We're on 11. Thank you.
- 14 Q. As a --
- MR. TISI: Is this the next one?
- MS. AHERN: Yeah. Hold on. I'm going
- <sup>17</sup> to clarify it.
- Q. So this photocopy that you made from
- Blaustein's came from the fourth edition?
- A. Correct.
- Q. The textbook that we have here marked as Exhibit 10.
- A. (Witness nodded.)
- Q. Okay. So Exhibit 11 are photocopies of
- <sup>25</sup> specific pages from Exhibit 10, which is

Page 98 <sup>1</sup> Blaustein's Pathology of the Female Genital

<sup>2</sup> Tract, Fourth Edition.

3 (Excerpt from "Blaustein's

4 Pathology of the Female Genital Tract,"

5 Fourth Edition, marked Exhibit 11.)

6 BY MS. AHERN:

10

11

Q. Okay. And can you tell me, with

8 Exhibit 11, the specific information that you

found relevant to your opinions in this case?

A. Okay. So on Page --

MR. ROTMAN: You marked the copy as

12 Exhibit 11 and the book as Exhibit 10?

13 MS. AHERN: Mm-hmm.

14 MR. ROTMAN: Okay.

15 A. Okay. You have to bear with me,

<sup>16</sup> because I don't have any highlights or anything,

so I have to find it.

18 So Page 376, right down -- okay. The last

paragraph under "Zanko Granulomatous

20 Inflammation," it says, "Rarely, talc or another

21 foreign substance may elicit a foreign-body

22 reaction in the endometrium. Talc may be

<sup>23</sup> introduced into the endometrial cavity by

24 instruments contaminated with talcum powder or by

gloves during a pelvic examination. Patients may

Page 99

<sup>1</sup> be asymptomatic or may have menorrhagia.

<sup>2</sup> Microscopically, the extent of the granulomatous

<sup>3</sup> inflammatory reaction depends on the quantity of

<sup>4</sup> talc inoculated. The infiltrate is characterized

<sup>5</sup> by histiocytes and foreign-body multinucleated

<sup>6</sup> giant cells surrounding the talc crystals, along

<sup>7</sup> with lymphocytes and plasma cells. The crystals

8 appear as refractile, birefringent, needle-like,

or fan-shaped splinters in polarizing light."

10

Then on Page 530 --

11 Q. Sorry. Let me just -- let's take this 12 in order.

So what about that particular passage

informs your causation opinions regarding talc

and ovarian cancer, if at all?

A. So it is evidence that talc causes

foreign-body giant cell reaction and chronic

inflammation in the endometrium.

19 O. And that is the uterine tissue;

correct?

16

25

21 A. That's the lining of the uterus,

22 correct.

Q. And how does that inform your opinions 23

24 regarding the development of ovarian cancer?

A. Well, I thought, again, it's a piece of

Page 100

<sup>1</sup> evidence, and it shows that talc can cause

<sup>2</sup> granulomatous or chronic inflammation in the

<sup>3</sup> female reproductive tract.

Q. And how is uterine cancer related to,

for instance, high-grade serous carcinoma of the

A. Again, this is just evidence that talc

can cause chronic inflammation and granulomas in

the endometrium, which I think is another piece

of evidence that talc can cause chronic

inflammation and granulomatous inflammation in

the female reproductive tract.

13 Q. Doctor, shouldn't talc -- based on the

literature that we have available to us over the

last 50 years, shouldn't talc induce that

response in any tissue that it's found in?

A. Well, again, different tissues will

respond in different ways, but I think it also

depends -- well, I'll just...

Q. Well, as a pathologist --

MR. ROTMAN: Wait. Wait. Are you

22 done?

20

21

25

23 MS. AHERN: Are you done?

THE WITNESS: I think so.

Q. Okay. So as an anatomic pathologist

Page 101

<sup>1</sup> who knows something about granulomatous

<sup>2</sup> reactions, shouldn't a foreign body produce a

<sup>3</sup> foreign-body reaction in any tissue that it's

4 found in?

A. Not -- no, not always. Sometimes you

6 will have a foreign body that won't cause a

<sup>7</sup> foreign-body giant cell reaction. It depends

8 on -- it depends on the particle, the foreign

body, the tissue it's in. You don't always see

10 that. And also the timing, when you're looking

at it, versus how long it's been there.

Q. Well, the timing is just more or less

when you observed it, not whether it occurred;

correct?

15

25

MR. ROTMAN: Objection.

16 A. So it's hard to know whether or not it

occurred -- if it had been there for a long time

and you're looking years, you know, in -- years

after it's been there, if you don't see a

granulomatous or chronic inflammation, that's not

evidence that it never occurred; it's just you're

not seeing it at that moment.

Q. Do you know of any -- any foreign 23

24 bodies that generate tissue-specific reactions?

A. Well, we -- I mean, we certainly have

- evidence with, say, viruses and bacteria that
- <sup>2</sup> respond differently -- certain tissues will
- <sup>3</sup> respond differently to different infections.
- For esophageal cancer, there's some
- <sup>5</sup> literature to suggest that very hot liquids
- <sup>6</sup> increase your risk of esophageal cancer. So,
- <sup>7</sup> yes, certain tissues will respond differently to
- <sup>8</sup> different material.
- 9 Q. So my question was -- it might be just
- <sup>10</sup> a little simpler to think of just this
- 11 question -- do you know of any foreign bodies --
- 12 I'm not talking about viruses and bacteria which
- 13 cause immune responses -- but foreign bodies that
- <sup>14</sup> generate a tissue-specific foreign-body reaction?
  - A. Well, it's sort of semantics. I mean,
- <sup>16</sup> viruses and bacteria -- that's why I answered the
- way I did -- are foreign to -- and, certainly,
- <sup>18</sup> foreign bodies can elicit immune response.
- 19 That's why you see granulomatous reactions and
- <sup>20</sup> chronic inflammation.
- So I guess I'm not -- I think I answered the
- <sup>22</sup> question.

15

- Q. Pathologists distinguish the different
- 24 types of granulomatous inflammation based on the
- <sup>25</sup> cause of the inflammation; correct?

- Page 104
- <sup>1</sup> granulomas, which are caused by talc and
- <sup>2</sup> cornstarch and certain other inert-type
- <sup>3</sup> materials; correct?
- MR. ROTMAN: Objection.
- A. Again, you can have inflammation --
- <sup>6</sup> granulomatous inflammation due to infection, you
- <sup>7</sup> can have granulomatous infection -- response due
- 8 to foreign bodies, and you can have granulomas in
- <sup>9</sup> certain diseases, like sarcoidosis or Crohn's
- o disease.
- So in that respect, yes, we're categorizing
- granulomas, but on a daily basis, other than that
- 13 type of breakdown, we're not subcategorizing
- <sup>14</sup> granulomas.
- Q. But you are aware of the literature
- <sup>16</sup> that actually characterizes the different types
- $^{17}\,$  of granulomas and the types of cells that are
- 18 involved in the formation of those granulomas;
- 19 correct?
- A. As far as foreign-body giant cells and
- multinucleated giant cells and inflammatory
- <sup>22</sup> versus foreign body, yes.
- Q. So, you know, a granuloma caused by
- 24 tuberculosis is going to be very different from a

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<sup>5</sup> granuloma caused by talc; correct?

- A. We look for -- if we see granulomatous
- <sup>2</sup> inflammation in tissue, we certainly look for a
- <sup>3</sup> potential cause. We want to rule out infection,
- <sup>4</sup> so if we see granulomas, we'll routinely do
- <sup>5</sup> special stains to rule out infection. Like we'll
- <sup>6</sup> do an acid-fast Bacillus stain for microbacteria.
- <sup>7</sup> We'll do fungal stains to rule out a fungal
- <sup>8</sup> infection that causes inflammation.
- 9 And then, of course, if we have -- if those
- <sup>10</sup> are negative and we're trying to figure out if
- 11 there's a foreign body within a granuloma, we can
- 12 use polarized light to try to find the foreign
- body to identify it as a foreign-body giant cell
- <sup>14</sup> reaction.
- But often you do have granulomatous
- <sup>16</sup> inflammation and you won't find fungi -- fungal
- <sup>17</sup> lesions -- fungal bodies or bacteria or
- <sup>18</sup> birefringent particles on them, so you don't
- 19 necessarily know why you have a granulomatous
- <sup>20</sup> inflammation.
- Q. Pathologists categorize granulomatous
- <sup>22</sup> inflammation, don't they? They categorize it in
- 23 terms of the different types of immune granulomas
- $^{\rm 24}~$  and the etiologic agents for those granulomas,
- <sup>25</sup> and over here somewhere are the foreign-body

- MR. ROTMAN: Objection.
- A. I would say not necessarily. In
- 3 microbacterial infections, you can have necrosis
- 4 within granulomas, but that doesn't mean that
- 5 you're not necessarily going to see necrosis in a
- 6 foreign-body granuloma.
- Q. How often have you seen necrosis
- 8 associated with a foreign-body granuloma?
- A. I'd say more commonly you see
- 0 necrotizing or necrotic granulomas in infectious
- 1 granulomas.
- Q. There are different types of
- 13 macrophages that are involved, too, in
- 14 foreign-body granulomas and in immune granulomas;
- 15 correct?
- A. As far as macrophages themselves and
- 17 multinucleated giant cells that can form
- 18 granulomas.
- Q. There are different types, different
- 20 subtypes of macrophages that are involved in --
- 21 A. Yes.
- Q. -- those activities; correct?
- 23 A. Yes.
- Q. Okay. So there are differences between
- <sup>25</sup> a foreign-body granuloma and an immune granuloma?

Page 106 A. There can be.

Q. Well, there are, aren't there? I mean,

<sup>3</sup> there are papers that characterize these. A. Yes, but I'm -- yes. In the

<sup>5</sup> literature, yes. And -- but are we necessarily

<sup>6</sup> categorizing them when we're looking at a

particular patient? We're looking for the cause

of the granuloma, but we're not necessarily

subcategorizing, is my point.

O. Understood.

1

10

11 Oh, I'm sorry. We were talking about the <sup>12</sup> pages that you copied from Blaustein's.

What was the second page in that photocopy, 14 Exhibit 11?

15 A. Okay. So Page 539.

16 O. What was it on 539 that's relevant to your opinions in this case?

A. Okay. I think it starts at the very bottom. I think it carries into Page 540, where

<sup>20</sup> it starts talking about foreign-body reactions in

<sup>21</sup> the -- this is diseases of the fallopian tube. 22

So it starts, "Foreign material may be

<sup>23</sup> introduced into the tube in the course of

gynecological investigation, especially

<sup>25</sup> hysterosalpingography, lubricant jelly, mineral

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- <sup>1</sup> oil, and starch and talc powder may cause lipoid
- <sup>2</sup> or granulomatous salpingitis. Talc may cause
- <sup>3</sup> mucosal or serosal granulomas. Examination of
- 4 all granulomas or foreign-body reactions under
- <sup>5</sup> polarized light is useful in the recognition of
- 6 these processes."
- So, again, I'm just referencing the fact
- that talc can cause granulomatous reaction in the
- 9 fallopian tube.
- 10 Q. So another tissue that's exposed to
- talc forms the typical type of foreign-body
- 12 response?

13

- A. That can form a granulomatous reaction.
- Q. Okay. And does that in any way inform
- <sup>15</sup> your opinions on causation, other than
- granulomatous reactions occur?
- 17 A. Well, so, again, it's another piece of <sup>18</sup> evidence that talc can cause a granulomatous
- reaction within the female reproductive tract.
- Now, the fallopian tube, we know some -- has
- 21 been indicated as a precursor site for certain
- <sup>22</sup> high-grade serous carcinomas, so I think it's
- relevant. 23
- 24 But, again, you know, we're talking about
- <sup>25</sup> mechanisms that talc may eventually cause ovarian

Page 108

- <sup>1</sup> cancer, which is sort of the plausibility arm of
- <sup>2</sup> the Bradford Hill. I think it's compelling
- <sup>3</sup> evidence that we see that you can get
- granulomatous inflammation and some of these
- sections have mentioned lymphocytes and plasma
- 6 cells in the tissue. I mean, I think it's a
- further piece of evidence that talc can cause
- these -- this type of inflammation in female
- reproductive market.
- Q. How often have you, in your career, seen a talc granuloma in gynecologic specimens?
- A. We don't routinely do -- perform
- polarized light microscopy on ovarian tumors,
- partly because you really need electron
- 15 microscopy. You can -- with polarized light
- microscopy, you can tell that there's a foreign
- substance there, but that's pretty much as far as
- you can -- you can get. You need more testing to
- be able to determine what type of particle it is,
- usually. So we don't, in daily practice,
- routinely use polarized light microscopy.
- 22 Now, it's entirely possible that, you know,
- in the course of my career, I've come across
- chronic inflammation or granulomas in an ovarian
- tumor that could have been due to talc that I

Page 109

- <sup>1</sup> didn't polarize so I didn't see particles, I
- <sup>2</sup> guess.
- Q. So let me back up and just ask you:
- 4 How often in your career have you seen
- <sup>5</sup> foreign-body granulomas? Regardless of whether
- <sup>6</sup> you've identified the particle in the granuloma,
- how often have you seen foreign-body granulomas
- in gynecologic specimens? Not just tumors, but
- any gynecologic specimens you've reviewed.
  - A. No, I understand.
- 11 O. Okay.

10

- 12 A. You can certainly see granulomas -- how
- often, I can't give you a number; that would just
- be wildly guessing -- but you can see granulomas
- in the endometrium. You can see them in
- different types of tumor.
- 17 Sometimes it's -- you'll see granulomas, but
- you won't see a particle, so you don't know for
- sure if it's a foreign-body granuloma; you just
- see the granuloma because you're not using
- polarized light microscopy on it.
  - MR. KLATT: Object. Nonresponsive.
- 23 MS. AHERN: Same.
- 24 Q. So how often, though, in your career --<sup>25</sup> you can give me an estimate -- have you seen

Page 110 1 foreign-body granulomas in gynecologic specimens? <sup>1</sup> foreign body, you're not necessarily going to be 2 MR. ROTMAN: Objection. <sup>2</sup> able to say whether or not it's a foreign-body Q. I'm not talking about immune granuloma with absolute certainty unless you're granulomas, but just foreign-body granulomas. 4 looking under polarized light microscopy. And even then, you might not see it under polarized We'll start there. MR. ROTMAN: Objection. You've asked 6 light microscopy, because it depends on the section of the tissue you're looking at and -that question. She's answered it. A. So, again, I've seen granulomas in my Q. Okay. Thank you. <sup>9</sup> career in the female reproductive tract, but I And if you see a foreign-body response in 10 don't -- pathologists don't routinely use tissue, do you then go one step further and polarized light microscopy in that instance to polarize to see if you can identify whether 12 look for foreign bodies. that's got a foreign body in it? 13 13 Q. Okay. So are you done? A. It certainly depends on the situation. 14 14 MR. ROTMAN: Can we take a break? So, for example, in cases where there's been 15 MS. AHERN: Not just yet. Let me a surgery and they've taken out more tissue after 16 finish this line of questioning and then we can surgery, you might be looking for polarizable foreign body. Often, you can see a suture on take a break. Because we may want to -- what time is it? light microscopy. But, yeah, we do -- depending 19 MR. ROTMAN: It's been an hour. on the situation, we will use polarized light 20 MS. AHERN: 11:30. If we go a little microscopy to find foreign bodies. bit longer, we can break for lunch if you want. 21 MR. ROTMAN: Okay. 22 MR. ROTMAN: I just want to take a 22 Q. How often do you polarize specimens <sup>23</sup> where you've found a foreign-body response? How break in the next few minutes.

> Page 111 Page 113

A. I think -- I think I tried to come up

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## <sup>1</sup> BY MS. AHERN:

24

25

Q. Doctor, are you able, as a -- as a <sup>3</sup> pathologist, under regular light microscopy to 4 identify a foreign-body granuloma? Not the content, just the foreign-body granuloma.

MS. AHERN: Sure.

A. I would say it depends on the specific granuloma. Sometimes, for example, in epidermal inclusion cysts, you can see the keratin under

<sup>9</sup> light microscopy that's causing the reaction, but 10 you don't always -- you won't always necessarily

11 see a particle. They're very small. And unless 12 you're looking specifically for polarizable

<sup>13</sup> birefringent particles, you're not going to see

<sup>14</sup> it just with regular light microscopy.

Q. So my question wasn't -- and I thought <sup>16</sup> I was specific -- my question wasn't whether or not you could see the particle; my question was:

18 You should be able to see the foreign-body

19 response in terms of multinucleated giant cells. 20 Do you -- can you see that under regular

21 light microscopy?

A. Well, so you're categorizing it as a 22 <sup>23</sup> foreign-body granuloma. What I'm saying is you 24 can see granulomas, of course, under light

<sup>25</sup> microscopy. But if you're not looking for a

<sup>1</sup> with an estimate. I think I have it in my

<sup>2</sup> report, actually, in the beginning.

often do you do that?

Yes. So I estimated that I use polarized

<sup>4</sup> light microscopy for this purpose, which is identifying foreign material to explain an

<sup>6</sup> inflammatory reaction, I estimated about twice a month. It's an estimate.

And I -- well, that was -- actually, I was

referring to calcium oxalate crystals in breast

biopsies. That's different. So it's not

uncommon, let's put it that way, but I can't really give you a -- an estimate.

13 Q. What was the estimate for breast tissue?

15 A. I think it was twice a month, is what I 16 said.

17 O. So compared to looking for calcium crystals in breast tissue twice a month, how often in gynecologic specimens do you look for foreign bodies?

21 A. I would say slightly less than that.

22

23

Q. Maybe once a month, maybe less than that?

24 A. Once a month is probably a good <sup>25</sup> estimate, I guess.

Q. Do you know, based on your review of the epidemiologic literature, what proportion of

3 women are said to use talc?

A. I believe I've seen in some of the

<sup>5</sup> literature -- it depends on the population, I

6 think. I think I saw -- well, again, I'd have to

<sup>7</sup> pull out the papers to be absolutely certain, but

8 I remember there was a reference to

<sup>9</sup> African-American women, about 50 percent of them

10 using talc.

Q. Would you say that in 50 percent of the

12 gynecologic specimens you review, you find

13 foreign-body granulomas or granulomas?

A. Well, I wouldn't necessarily expect --

15 I wouldn't expect to, just because, you know,

<sup>16</sup> again, we're looking at an ovarian tumor at a

very particular point in time.

How many granulomas -- how much talc is

19 getting to the ovary, we don't -- we don't know

20 how much talc is getting to the ovary. We know

21 it's been found there, we know it can get there,

22 but we don't know with how much use, how much is

<sup>23</sup> actually getting there.

So we wouldn't necessarily find a lot of

granulomas in ovarian tissue of women that use

Page 116

I mean, it's not -- it's not frequent that

<sup>2</sup> you're going to find foreign-body giant cell

<sup>3</sup> reactions in tissue, but, again, it doesn't mean

<sup>4</sup> that they weren't there. Maybe --

Q. And this is based just on your

<sup>6</sup> experience. I know that -- I don't want you to

<sup>7</sup> guess about what might have been there --

A. Yeah, I'm --

<sup>9</sup> Q. -- but based on your experience as a

practicing pathologist.

11 A. It would just be a pure guess at this

 $^{\rm 12}\,$  point. I couldn't give you an accurate number.

Q. Do you see foreign-body reactions in

<sup>14</sup> 50 percent of the gynecologic specimens or cases

that you review?

16

21

24

MR. ROTMAN: Objection.

A. I would say it's less than 50 percent.

Q. Is it less than 25?

A. I would say less than 25.

Q. Less than ten?

A. Probably less than ten.

Q. Less than five?

A. That's where I'm not exactly sure.

Q. Okay.

MS. AHERN: All right. We can go ahead

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<sup>1</sup> it, because we don't know exactly how much is

<sup>2</sup> getting there or we don't know how long those

<sup>3</sup> granulomas are there once the tissue is in the

<sup>4</sup> ovary.

I mean, 20 years later, when you're looking

6 at the -- at the ovary for a talc particle that's

<sup>7</sup> been there, we don't know if the granuloma would

<sup>8</sup> still be there or the chronic inflammation would

<sup>9</sup> still be there.

Q. And my question wasn't specific to

ovarian tissue; it was just gynecologic

<sup>12</sup> specimens.

10

16

17

22

Because you review more than ovarian tissues

when you're looking at gynecologic samples;

15 correct?

A. Yes.

Q. So looking at all of your gynecologic

18 specimens, your vaginal, vulvar, endometrial,

19 tubal, ovarian, I guess omentum might fall in

20 there, how often do you identify foreign bodies

<sup>21</sup> or foreign-body granulomas?

A. I would have to be -- a completely

<sup>23</sup> ballpark guess, but, I don't know, maybe every --

<sup>24</sup> I'm really trying to figure out a somewhat

<sup>25</sup> ballpark figure. It's tough.

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<sup>1</sup> and take a break. Thank you.

THE VIDEOGRAPHER: Here ends Media 2.

<sup>3</sup> Off the record, 11:44 a.m.

(A recess was taken.)

THE VIDEOGRAPHER: Here begins Media

<sup>6</sup> No. 3 in today's deposition of Sarah Kane, M.D.

<sup>7</sup> Back on the record, 12:02 p.m.

8 BY MS. AHERN:

9 Q. All right. Doctor, can we go ahead and

10 keep moving through that photocopy, Exhibit 11.

11 Can you tell me what the next page was?

A. Okay. We just read from Page 540, I

believe, so the next one is Page 648.

4 Q. Okay. And tell me what on 648 caught

15 your eye.

A. Okay. It's the first paragraph under

7 "Noninfectious Granulomatous Peritonitis." So it

<sup>8</sup> says, "Foreign material typically recognizable on

histologic examination can elicit a granulomatous

reaction on the peritoneum. Starch granulomas

from surgical gloves, douche fluid, and

22 lubricants typically incite a granulomatous and

<sup>23</sup> fibrosing peritonitis. In occasional cases, the

inflammatory reaction may be a tuberculoid type

<sup>25</sup> with KCS necrosis. The periodic acid shift (PAS)

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1 positive starch granules exhibit the

<sup>2</sup> characteristic Maltese cross configuration" --

THE COURT REPORTER: I'm sorry, you're

<sup>4</sup> reading too fast.

THE WITNESS: I'm sorry.

6 A. "The periodic acid shift (PAS) positive

starch granules exhibits a characteristic Maltese

8 cross configuration under polarized light. Talc

<sup>9</sup> was once an important cause of granulomatous and

10 fibrosing peritonitis because of its use as a

11 lubricant on surgical gloves and talc-induced

12 peritonitis has been described more recently in

 $^{13}\,$  drug abusers." I think that's kind of where it

14 stops.

5

Q. Okay. And how does that passage that

16 you just read inform your opinions in this case?

A. Well, again, it's just another --

18 similar to the last pieces, this is the

<sup>9</sup> peritoneum, so this is outside of the fallopian

20 tube. Once particles are outside of the

21 fallopian tube, they are in the peritoneum.

22 That's where the ovary is. And so it's

<sup>23</sup> discussing foreign-body granulomatous reactions

<sup>24</sup> in the peritoneum.

Q. And this question -- this passage that

<sup>1</sup> head.

Q. And when you say "they" were looking

Page 120

Page 121

<sup>3</sup> at, are you talking -- who are you talking about?

A. When the -- when the regulatory -- if I

<sup>5</sup> recall -- did I put that in my report? -- they

<sup>6</sup> removed -- I know that they removed starch from

<sup>7</sup> surgical gloves because it was causing an

8 inflammatory reaction.

And they had started using starch more

o commonly because talc had been removed from

surgical gloves for also causing inflammatory

<sup>2</sup> reactions.

Q. And talc particles and cornstarch

particles cause the same foreign-body reaction in

the peritoneum and fibrosis; correct?

A. Well, again, they can cause a

<sup>17</sup> granulomatous reaction, but they're

<sup>18</sup> bioabsorbable, so it's not going to be -- you

<sup>19</sup> know, when we're talking about talc, we're

<sup>20</sup> talking about the talc in surgical gloves. And,

21 you know, talc is not bioabsorbable and it will

22 stay in the peritoneum longer than starch, which

23 is bioabsorbable. So it will -- the inflammation

<sup>24</sup> will likely resolve more quickly. It's a

<sup>25</sup> different -- it's a different type of reaction

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<sup>1</sup> you just read also mentions that starch granules

<sup>2</sup> from surgical gloves --

<sup>3</sup> A. Yes.

Q. -- cause granulomatous and fibrosing

<sup>5</sup> peritonitis, which is the same that they mention

6 talc use to.

Would you say that starch granules, then,

8 have the capacity to cause chronic inflammation

<sup>9</sup> that can lead to cancer?

A. Starch can cause inflammatory

11 reactions, but it's a -- very different, in that

12 it's bioabsorbable, and so the particles are

<sup>13</sup> absorbed in the body. And the literature hasn't

<sup>14</sup> supported a link between starch and ovarian

15 cancer.

10

16

17

Q. How many studies have evaluated the association between starch and ovarian cancer?

A. I couldn't say, off the top of my head,

19 how many. But I know, you know, they looked at

<sup>20</sup> starch when they were evaluating whether or not

21 to remove it from surgical gloves, and they ended

<sup>22</sup> up deciding to remove it from surgical gloves.

And I -- I think at that point they had done

<sup>24</sup> a literature search. I don't think there was --

<sup>25</sup> I don't know how many studies off the top of my

<sup>1</sup> because it's bioabsorbable.

Q. Well, they both cause granulomas;

3 right?

4 A. Mm-hmm.

Q. And they both cause fibrosis; correct?

6 A. They can cause fibrosis.

Q. Does the biodurability of the causative

8 agent determine how long fibrosis exists?

A. Well, the fibrosis is thought to arise

from the inflammatory process. And since -- I

11 don't know how much data is really there except

12 to say that starch is bioabsorbable and talc is

13 not. So talc is going to be available for an

inflammatory response more than a starch particle

15 will.

20

Q. Is the purpose of a foreign-body

granuloma to essentially wall off an irritant, a

18 foreign body, from the rest of the tissue to

prevent damage?

A. That can be one reason.

Another reason is if the particle is large

22 enough and one macrophage can't handle it because

23 of its size, it will sort of recruit more

24 macrophages to the area to try to digest the

<sup>25</sup> foreign material, which is not going to -- they

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1 won't be able to digest the talc particle.

- Q. If they can't digest the particle,
- <sup>3</sup> these macrophages will fuse to form a
- 4 multinucleated giant cell and surround the
- <sup>5</sup> particle to basically encapsulate it and prevent
- 6 it from harming the surrounding tissue; correct?
- A. It's possible that they would, yes,
- 8 they would recruit more macrophages and
- <sup>9</sup> potentially do that.
- Q. Isn't that the purpose of a
- <sup>11</sup> foreign-body granuloma?
- A. So, again, you can get well-formed --
- 13 you can get well-formed encapsulated granulomas.
- 14 You can also get sort of poorly formed granulomas
- $^{15}$  that are -- when more macrophages have been
- <sup>16</sup> recruited to that site.
- You can get a -- you can get a histiocytic
- 18 reaction that isn't a well-formed granuloma in
- 19 the sense that you're talking about, where it's
- <sup>20</sup> kind of walling off the foreign body. You can
- 21 get histiocytic reactions that aren't as well
- 22 formed like that.
- Q. But we're just talking about the actual
- granuloma itself, those particles that do result
- <sup>25</sup> in a well-formed granuloma.

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- Once that granuloma has formed, it can
- persist for many years, can't it, without
- <sup>3</sup> damaging the surrounding tissue?
- MR. ROTMAN: Objection.
- 5 A. I think it would depend. Macrophages
- 6 have a certain lifespan, so it's going to be
- <sup>7</sup> constantly recruiting different macrophages to
- <sup>8</sup> that site.
- 9 So I don't think we can say for certain that
- 10 the -- in fact, I think the body is still
- 11 reacting to that foreign body if it's still
- 12 recruiting new macrophages in.
- Q. Do you know that for a fact based on
- 14 your reading of the literature of granulomas,
- 15 that that's the mechanism behind a foreign-body
- <sup>16</sup> granuloma, as opposed to an immune granuloma?
  - A. What I'm saying is -- is that
- 18 macrophages have a certain shelf life, and so
- 19 they will constantly recruit new macrophages to
- <sup>20</sup> that area.

17

- Now, whether or not there's an exposure in
- 22 that particle while it's in that process, I don't
- $^{23}$  think we can definitively say.
- Q. Can you cite to any papers that support
  - <sup>5</sup> your understanding of that process whereby

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- <sup>1</sup> macrophages are continuously recruited to
- <sup>2</sup> foreign-body granulomas?
- A. I know that I've read it in the course
- <sup>4</sup> of my daily practice. I can search at some point
- <sup>5</sup> for it, but I know that that's the case, because
- <sup>6</sup> I know that macrophages, again, have a certain
- <sup>7</sup> lifespan.
  - But, you know, again, the inflammatory
- <sup>9</sup> response, we also don't know how long that
- <sup>10</sup> inflammatory response is going to be there for
- 11 sure. Is it possible that at some point the
- 12 granuloma resolves and you get some fibrosis and
- the talc particle or whatever particle is there
- <sup>4</sup> remains? I think that's possible and likely, in
- <sup>15</sup> fact, because you do see resolution of granulomas
- <sup>16</sup> with fibrosis.

17

- Q. Is fibrosis associated with the
- <sup>-8</sup> development of ovarian cancer?
- A. There hasn't -- there hasn't been a
- 20 lot -- again, the causes of ovarian cancer are
- 21 sort of -- the literature and the research is
- 22 still bearing all of it out, but from what I know
- <sup>23</sup> of the literature, I don't think that they found
- <sup>24</sup> fibrosis itself being an increased risk factor
- <sup>25</sup> for ovarian cancer.

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- <sup>1</sup> Q. Is fibrosis associated with chronic
- <sup>2</sup> inflammation?
- <sup>3</sup> A. It can be, yeah. Chronic inflammation
- <sup>4</sup> can lead to fibrosis.
- Q. Do you know of any literature that has
- 6 linked talc granulomas introduced into the body
- <sup>7</sup> through the use of talc-dusted surgical gloves
- 8 with any sort of cancer?
- <sup>9</sup> A. So we know that talc can -- there are
- studies that have shown talc in the ovaries, and
- we know that chronic inflammation has been
- 12 implicated in cancer.
- So if talc can reach the ovaries -- and we
- <sup>14</sup> also have evidence that talc causes chronic
- <sup>15</sup> inflammation. So if talc reaches the ovary, I
- think it's a plausible mechanism for talc from
- surgical gloves to cause an inflammatory reaction
- and lead to cancer. I think that's plausible.
- And, again, that's the plausibility arm of
- 20 it. You know, that's a piece of the general
- 21 causation opinion, but, you know, they're still
- piecing together a lot of the etiology of ovarian
- <sup>23</sup> cancer.

- Q. Then why --
  - MR. KLATT: Objection, nonresponsive.

Page 283 of 565 PageID: Page 126 Page 128 1 MS. AHERN: Nonresponsive, yeah. MS. AHERN: No. We're going back to 2 Q. Doctor, why are you so sure, then, that this question. <sup>3</sup> talc causes ovarian cancer? MR. ROTMAN: Okay. That's fine. A. It's --4 So you're asking her again a question 5 MR. ROTMAN: Objection. that she previously answered. A. So I can lay out to you my methodology. 6 MR. KLATT: No --<sup>7</sup> It's in the report. I did very in-depth, 7 MS. AHERN: I'm interested in --8 extensive review of the literature, which 8 MR. KLATT: -- a question she didn't <sup>9</sup> included the epi studies, animal studies, and answer. 10 <sup>10</sup> biologic studies. MS. AHERN: -- the question she didn't 11 And I think -- well, I know that the epi answer first. 12 studies have been very consistent with the BY MS. AHERN: 13 increased risk associated with talcum powder Q. Which is: "Do you know of any product usage -- I'm talking about talcum powder literature that has linked talc granulomas product, what's in the bottle -- and perineal introduced into the body through the use of <sup>16</sup> talc application with ovarian cancer. talc-dusted surgical gloves with any sort of And I think if you're looking at -- if you cancer?" <sup>18</sup> go through the methodology that I used and you're 18 Do you know or not know of any literature 19 looking at the Bradford Hill analysis, which I've that supports that? 20 20 laid out in the report, I've come to the A. Well, first of all, I think we're 21 professional -- you know, my professional 21 talking about -- you're talking about surgical <sup>22</sup> judgment is that the talcum powder products -glove talc, right, which is pharmaceutical-grade <sup>23</sup> weighing everything, that talcum powder products talc, which is different from the talcum powder <sup>24</sup> cause ovarian cancer. product that I'm opining about. And I know -- and, interestingly, about And we know that these talc particles can Page 127 Page 129 <sup>1</sup> three weeks after I wrote my report, there was 1 get to the ovary and we know that talc can cause <sup>2</sup> the Health Canada report that, in reading their <sup>2</sup> chronic inflammation. <sup>3</sup> methodology and the literature that they Q. Doctor, first question about your <sup>4</sup> reviewed, was very similar to what I reviewed and 4 answer is: What makes you think that cosmetic <sup>5</sup> talc used in Johnson & Johnson baby powder is not <sup>5</sup> my methodology. And they came to the same <sup>6</sup> conclusion. pharmaceutical-grade talc? A. I'm talking about the product, the 7 MR. KLATT: Objection. 8 MS. AHERN: Objection. Nonresponsive. ultimate product. 9 9 Q. Doctor, my question was: Do you know Q. Johnson's baby powder; correct? 10 10 of any literature that has linked -- sorry. A. Whatever is in the bottle.

- 11 My first question we're going to go back to
- 12 now is: Do you know of any literature that has
- 13 linked talc granulomas introduced into the body
- through the use of talc-dusted surgical gloves to
- <sup>15</sup> any sort of cancer?
- 16 MR. ROTMAN: Objection.
- 17 MS. AHERN: What's the objection?
- 18 MR. ROTMAN: Your question was --
- 19 MS. AHERN: I'm reading it.
- 20 MR. ROTMAN: -- why are you so certain.
- 21 MS. AHERN: Well, I just told you we're
- going back to this question. 22
- 23 MR. ROTMAN: Okay. So you're asking --
- you're not saying that she didn't -- you're not
- <sup>25</sup> repeating your former question?

- 11 Q. You're saying that's not
- pharmaceutical-grade talc?
  - A. Whatever is in the bottle.
- 14 Q. Okay.
- 15 A. So --

- Q. What is your -- what is your
- understanding of what pharmaceutical-grade talc
- is and how is that different from what's in
- Johnson's baby powder?
- A. So I didn't opine on the constituents
- of the talcum powder that -- the baby product --
- talcum powder products, the Johnson & Johnson. I
- saw evidence as to what's in the talcum powder
- products, but I didn't do my own analysis as to
- what is in the talcum powder products.

- 1 But pharmaceutical-grade talc, if we're
- <sup>2</sup> talking about talc that's used in pleurodesis,
- <sup>3</sup> for example, is going to be different than talcum
- powder products in the bottle --5
  - Q. Okay.
- 6 A. -- cosmetic talcum powder products.
- Q. So how is it different?
- A. So, again, I didn't do my own analysis
- as to what is in the talcum powder product, but
- 10 that's what I am -- that's what my general
- <sup>11</sup> causation opinion is on, is the talcum powder
- 12 product in the bottle, that regular perineal use
- <sup>13</sup> of that causes ovarian cancer.
- Q. My question to you is: What do you <sup>15</sup> understand the difference between the talcum
- powder products and pharmaceutical-grade talc --
- 17 MR. ROTMAN: Objection.
- 18 Q. -- to be?
- 19 A. So I've seen evidence that in talcum
- 20 powder products, there are heavy metals. There
- are fragrances that are added to the talcum
- powder product that, in talc used for
- pleurodesis, they wouldn't be adding fragrances
- <sup>24</sup> to that type of talc.
- Q. Would -- you're not saying that talcum

- A. Well, I think I've answered, like, to
- <sup>2</sup> me, it doesn't -- it doesn't really matter
- <sup>3</sup> what -- the difference between pharmaceutical

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- <sup>4</sup> talc and talcum powder products; it's whatever is
- <sup>5</sup> in that talcum powder products -- product,
- <sup>6</sup> whatever is in the bottle that women are buying
- off the shelf and applying to their perineum.
- MR. KLATT: Objection. Nonresponsive.
- MS. AHERN: Objection. Nonresponsive.
- Q. My question was -- originally was: Do
- you know of any literature that connects talc
- dust of surgical gloves and any sort of cancer.
- 13 And then you said, "First of all, I think
- we're talking about surgical glove talc, which is
- a pharmaceutical-grade talc, which is different from the talcum powder product that I'm opining
- about."
- 18 So what I'm asking you is: What is
- different about the talcum powder product that
- 20

24

- 21 A. It's what I'm opining about. You know,
- 22 I haven't --
- 23 Q. Right.
  - A. -- looked at the talc that's used for
- pleurodesis, for example. It's what I'm

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- 1 powder products that are sold to consumers have
- <sup>2</sup> been altered to add heavy metals, are you?
- A. Well, I've seen the report of
- <sup>4</sup> Dr. Crowley that looks at heavy metals and
- <sup>5</sup> fragrances in the talc, the baby product talc
- 6 powder that he examined. I did not do my own
- analysis of that.
- Q. Does pharmaceutical-grade talcum powder
- <sup>9</sup> also have associated metals and sometimes heavy
- 10 metals?
- 11 A. I'm not sure if I've seen data as to
- 12 what is specifically in pharmaceutical-grade
- 13 talcum powder, but, again, to me, what is
- 14 important is the ultimate product and what is in
- 15 that bottle. It can -- whether it's platy talc,
- <sup>16</sup> fibrous talc, asbestos, heavy metals, fragrance
- <sup>17</sup> metals.
- 18 I mean, to me -- you know, I've seen
- <sup>19</sup> evidence of those things in that product, but to
- 20 me, what I'm looking at is the final product when
- 21 it comes to causing ovarian cancer.
- Q. So what is different about that final
- <sup>23</sup> product and pharmaceutical-grade talc? What
- 24 specific components have been added to that that
- <sup>25</sup> affect your opinions in this case?

- <sup>1</sup> separating out.
- I've looked at the talcum powder product
- <sup>3</sup> that women use on their perineum, what they
- <sup>4</sup> bought off the shelf. I haven't looked at
- pharmaceutical-grade -- let me correct that --
- pleurodesis talc, for example. I have not looked
- at pleurodesis talc and ovarian cancer. I have
- not looked at any literature specifically on
- that. It's been the talcum powder products that
- women are buying off the shelf and using on their 11
  - perineum.
- 12 Q. So if I told you that Johnson's baby
- powder starts out as pharmaceutical-grade talc
- and that, beyond that, fragrance is added, would
- it be the fragrance that you're taking issue with
- that you believe is causally associated with the
- 17 development of ovarian cancer?
  - A. Again, I -- it's whatever is in that
- bottle. It could be platy talc, fibrous talc,
- asbestos, heavy metals, fragrance. It -- to me,
- it's the product, whatever the product is that
- they are using.

- Q. And you have done a biologic
- plausibility analysis for fragrances, for metals,
- <sup>25</sup> for asbestos, for fibrous tale, and for platy

Page 134 Page 136 1 talc --<sup>1</sup> consistency piece of it. A. So --Q. Can I ask you -- you can go through all 3 <sup>3</sup> of it if you want, but would you rather break it O. -- each one of those constituents? down piece by piece? A. So I have looked at evidence -- so <sup>5</sup> Dr. Crowley's report, I mentioned. I've looked MR. ROTMAN: She should answer your <sup>6</sup> at Dr. Longo's report. I've looked at Hopkins question. <sup>7</sup> and the Pier charts from their depositions. I'm MS. AHERN: I'm not sure she's 8 aware of evidence that these heavy metals and answering my question. My question was: How do <sup>9</sup> fragrances and asbestos are in there. you come up with causation when you don't know 10 However, I haven't done -- what I know, I what the exposure is? 11 looked at the -- I've looked at some literature 11 MR. ROTMAN: I think she's answering 12 the question. 12 and I've looked at the IARC categorization of the 13 13 heavy metals. I've looked at Dr. Crowley's MR. TISI: That wasn't the question. 14 report and I've done an extensive look at The question was: Do you need to know the agent? <sup>15</sup> asbestos and ovarian cancer. And she said the agent is the product. 16 But, ultimately, those are just pieces of 16 BY MS. AHERN: <sup>17</sup> biological plausibility. What I'm mainly -- what 17 Q. The agent is everything in it? 18 I am opining about is the ultimate product. And, A. Yes, the agent is whatever is in that 19 again, it can be platy tale, it can be fibrous talcum powder product. 20 <sup>20</sup> talc, it can be asbestos, it can be heavy metals. Q. So are you basing, then, your causation It's pieces of information that strengthen 21 conclusions on the epidemiologic literature 22 the plausibility. We know that asbestos causes 22 alone? 23 <sup>23</sup> ovarian cancer, that certain heavy metals are A. The epidemiologic literature is very <sup>24</sup> carcinogens, which the IARC categorized them as. comp- --25 25 So it's just -- it's just additional pieces of MR. ROTMAN: She was not done with her Page 135 Page 137 <sup>1</sup> information that strengthen the biological <sup>1</sup> earlier answer. Now you've gone two more beyond <sup>2</sup> it. <sup>2</sup> plausibility arm of it. Q. Doctor, how do you arrive at a MS. AHERN: She's answering. Why don't <sup>4</sup> causation conclusion without a well-defined agent you let her answer. If she wants to go back, she of exposure? 5 can. 6 MR. ROTMAN: Objection. MR. ROTMAN: No, I want her to go back. Q. Do you understand what I'm asking you? She was -- she was in the middle of going through 8 How do you arrive at your causation and her Bradford Hill to answer your earlier question conclusion when you're not sure what it is about and you cut her off. So she had covered strength 10 the talcum powder products that's actually of association. <sup>11</sup> biologically relevant? 11 BY MS. AHERN: 12 A. Well, I think -- well, strike that. 12 Q. Doctor, you can answer the question the 13 The epi studies are looking at the product way you want to answer the question. 14 that the women are using. So that is the agent. MR. ROTMAN: Now there's no question in 15 front of her. 15 It's the -- it's the total product. That is the 16 agent. 16 MS. AHERN: Well, because you 17 So when you're looking through -- let me interrupted it. 18 just -- so let's keep in mind that we're looking MR. ROTMAN: Let's go back to what the at that product. 19 question was before you cut her off. "Do you 20 And then if you go through my Bradford Hill understand what I'm asking you? How do you <sup>21</sup> analysis, you look at strength of association. arrive at your causation and conclusion when <sup>22</sup> And, overall, there's a consistent relative risk you're not sure what it is about the talcum <sup>23</sup> that's between 1 and 2. I would say it's, across powder products that actually biologically --<sup>24</sup> studies, averaging 1.3 to 1.4 relative risk, and <sup>24</sup> that are biologically relevant?"

25

25 that's consistent across studies. That's the

And then you gave -- then you started

- an answer about the epi studies are looking at
   the product that the women are using, and you
- were talking about strength of association and
- 4 then you said, "And that's consistent across
- <sup>5</sup> studies. That's the consistency piece of it,"
- <sup>6</sup> and then you were interrupted.
- So were you done with your answer to that earlier question?
- 9 THE WITNESS: I can continue, because I <sup>10</sup> think it's important.

I mean, I was -- my general causation opinion, the methodology I used was to answer the

question: Does perineal application of talcum
 powder products, the, you know, baby powder

<sup>15</sup> product that you buy off the shelf, does that

cause ovarian cancer? So it's whatever is inthat bottle.

So with the methodology that I used, looking at the epi data, but also considering the

Bradford Hill criteria -- which, you know,
 looking for specificity is another one. So most

22 of the studies showed a stronger -- a strong

23 association with serous ovarian cancer, but it

<sup>24</sup> was basically associated with epithelial ovarian

<sup>25</sup> cancer, so all groups of epithelial ovarian

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- <sup>1</sup> cancer. It was pretty specific, the epi data,
- <sup>2</sup> for that type of ovarian cancer.
- Temporality. If you look at that, I
- 4 mean, the case-control studies are retrospective
- reviews, so we know that they were using talc
   before their diagnosis of ovarian cancer.
- Biological gradient. For those studies
- that looked at a biological gradient, there was
- <sup>9</sup> an evident -- there was evidence of a
- 10 dose-response, not all of the times statistically
- 11 significant, but the trend -- you can see a trend
- 12 of a dose-response across studies.
- And then we get into the plausibility
- piece, which you've been discussing mostly so far
- 15 in this deposition, which has to do with the
- <sup>16</sup> plausible mechanism of talcum powder -- what I'm
- <sup>17</sup> thinking of, talcum powder products -- whatever
- 18 is in that bottle was what I'm looking at --
- 19 talcum powder products causing -- the
- <sup>20</sup> plausibility of it causing a chronic inflammatory
- <sup>21</sup> response, leading to ovarian cancer. We've been
- <sup>22</sup> discussing that quite a bit today.
- And then coherence. So I can refer again to my report. Coherence, in this context,
  - <sup>5</sup> means coherence between epidemiologic and

1 agc 140

- generally accepted knowledge of the disease inquestion.
- So we know that particles can reach the
- <sup>4</sup> ovary. We know that talc can cause chronic
- <sup>5</sup> inflammation. We know that chronic inflammation
- <sup>6</sup> is associated with certain types of cancer. We
- <sup>7</sup> know that certain types of ovarian cancer have
- 8 shown association with chronic inflammatory
- conditions.

O So, again, going through all this is

- <sup>1</sup> experiment and analogy, experiment with the
- <sup>2</sup> animal studies and the in vitro studies. And
- analogy, I used the example of asbestos, because
- <sup>14</sup> even though asbestos is -- you know, asbestos is
- chemically similar, you can have asbestos fibers
- and talc fibers, but it's a similar mineral
- 17 chemically, and we know that that is a
- 8 carcinogen. So that's part of the analogy.
- But, again, it's the whole picture. I
- mean, you look at the -- all of this data
- following my methodology and you apply the
- <sup>22</sup> Bradford Hill criteria guidelines -- the Bradford
- <sup>23</sup> Hill guidelines. And, looking at all that, my
- professional judgment is that the talcum powder
- <sup>25</sup> products can cause ovarian cancer.

- Q. Okay. Are you done? I don't want to interrupt you.
- A. I think I answered the question.
- Q. Okay. One of the things, and I guess a
- 5 major component of the talcum powder products,
- 6 would be talc; correct?
  - A. Presumably -- it's called talcum
- 8 powder, so presumably, talc would be a
- <sup>9</sup> constituent.
- Q. Do you know what percentage of talcum
  - powder products is talc?
- 12 A. Again, I did not do my own analysis as
  - 3 to how much tale was in that product.
  - Q. Do you know whether any of the heavy
- <sup>5</sup> metals that you looked at or were examined by
- other experts in this litigation, whether any of
- <sup>7</sup> those are known carcinogens for the ovary?
- A. So it's another piece of information.
- <sup>19</sup> There is not, to my knowledge -- looking at what
- the IARC looked at, there's not data right now on
- 21 those heavy metals and ovarian cancer, but
- 22 it's -- it's a -- it's a piece of the puzzle.
- 23 It's a piece of information.
- The IARC has called some of them
- <sup>25</sup> carcinogenic, some of them probably carcinogenic,

<sup>1</sup> so we know that they can cause cancer. And if <sup>2</sup> they're in the talcum powder products, then it's <sup>3</sup> just another piece to the puzzle of plausibility.

- Q. Are you saying that the probably <sup>5</sup> carcinogenic category for IARC means that they can cause cancer?
- A. Well, we can look at what the IARC 2A <sup>8</sup> categorization -- category actually says, what they break it down. But my understanding is <sup>10</sup> it's -- probably carcinogenic means it probably causes cancer, more likely than not, probably <sup>12</sup> causes cancer.
- O. How many categories does IARC have? 13
- 14 A. They have four.
- 15 Q. What is the -- what is Category 1?
- 16 A. Carcinogenic.
- 17 Q. Known to be carcinogenic?
- 18 A. Mm-hmm.
- 19 Q. And then the next?
- 20 A. Probably carcinogenic.
- 21 Q. And then?
- 22 A. Possibly carcinogenic.
- 23 Q. And then?
- 24 A. I think it's unclassifiable. I have to
- <sup>25</sup> look. But I think it's uncertain, basically.

- Q. And then what is the last? 1
- 2 A. And then known not to be carcinogenic.
- Q. How many agents are in the known not to
- 4 be carcinogenic category?
- A. Very, very few.
- 6 Q. One; right?
- A. That's plausible. I haven't looked at
- the list recently. 8
- Q. So going back to the major component, you don't know what percentage of talcum powder
- <sup>11</sup> products are actually talc?
- 12 MR. ROTMAN: Objection.
- A. I have not done my own analysis as to what the components are of that talcum powder -of the talcum powder products.
- 16 Q. Do you agree that carcinogens can be
- 17 organ specific? 18
- A. I will agree that certain tissues
- respond to certain things differently.
- Q. Do you agree that carcinogens can be 20 21 organ specific?
- 22 A. Certain tissues respond to certain
- <sup>23</sup> things differently. If you're casting that wide
- <sup>24</sup> a net to say that one specific carcinogen only
- <sup>25</sup> causes one type of cancer, I think that's a

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- <sup>1</sup> little too wide a net. I think science is always
- <sup>2</sup> evolving and there's always the possibility of an
- <sup>3</sup> unknown cause of a certain type of cancer.
  - MS. AHERN: Objection. Nonresponsive.
- Q. My question was just: Can carcinogens <sup>6</sup> be organ specific?
  - A. And I feel like I answered that fairly.
- Q. Do you know of carcinogens that are
- organ specific?
- A. I know -- for example, we know that H. Pylori causes increased risk of gastric cancer, <sup>12</sup> but not oral or esophageal cancer.

We know that HPV infection can cause cervical cancer, anal cancer, certain types of squamous cell carcinomas of the oropharyngeal system, but not, you know, of the endometrium, for example.

So we know that certain things cause certain cancers and aren't -- haven't been associated with other types of cancers. But to cast that wide a net, to say that a carcinogen is only going to cause one type of cancer or this cancer is caused only by this carcinogen, I think that's <sup>24</sup> too wide a net, because I feel like research is constantly evolving. We're constantly learning

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<sup>1</sup> of new causal factors in cancer.

Q. Do you think that dose is an important consideration when you're looking at the

toxicologic effects of an agent on a tissue?

A. I think it is a piece of information.

<sup>6</sup> I'm looking at my biological gradient portion of my report, and I said in my report that it was an

important factor in my analysis because it does

add information to the overall causality.

- Q. Are there agents that can be toxic at <sup>11</sup> certain levels and not toxic at other levels?
- 12 A. There are certainly agents that are more toxic with increased exposure and increased duration. We don't know all of the thresholds for carcinogenicity of all carcinogens.
- 16 Q. As part of the biologic plausibility analysis that you would do on a particular agent, would that take into consideration the relative levels of exposure that a person would have to that agent?
- A. Well, dose-response -- I -- I'm taking 22 it -- your question -- can you rephrase the
- question? I'm sorry. I just want to make sure
- I'm answering it accurately.

25

Q. To determine whether it's biologically

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1 plausible for a particular agent to cause a

- <sup>2</sup> particular harm, would you need to be able to
- <sup>3</sup> characterize the dose of that agent that is
- <sup>4</sup> required to elicit the effect that you're looking
- 5 for?
- 6 A. I think it's a piece of the
- <sup>7</sup> information -- a piece of information, but you're
- 8 not always going to be able to determine a
- <sup>9</sup> dose-response. It's going to depend on the
- <sup>10</sup> carcinogen, the agent, the routes of exposure.
- 11 You're just not always going to have that data,
- 12 unfortunately. It would be nice to have, but
- 13 you're not always going to have it, and you don't
- 14 necessarily have to have it to come to
- <sup>15</sup> plausibility.
- Q. And do you have well-characterized
- 17 levels of exposure to the ovaries for women who
- <sup>18</sup> are using talc perineally?
- MR. ROTMAN: Objection.
- A. So some of the -- we're never really
- 21 going to be able to figure out what an actual --
- 22 to characterize what an actual dose -- dose of
- 23 talcum powder product of what -- of a talcum
- <sup>24</sup> powder product in a particular use. We don't
- 25 know how much a woman is putting on her hand to

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- <sup>1</sup> and ovarian cancer. I certainly saw some of the
- <sup>2</sup> data about talc migration and cornstarch on
- <sup>3</sup> surgical gloves migration, but I didn't
- <sup>4</sup> specifically -- I don't know if -- I don't even
- <sup>5</sup> know if that study has really been done.
- Q. Did you consider the publications on
- <sup>7</sup> talc responses -- or, excuse me, did you consider
- 8 the publications on granulomatous reactions to
- <sup>9</sup> talc from surgical gloves to be relevant to your
- biologic plausibility analysis?
- A. It's a piece of information that
- 12 talc -- now, again, surgical glove talc, for me,
  - is different than the talcum powder products.
- You know, my general causation opinion -- I
- <sup>15</sup> just want to be clear -- is about, you know,
- 16 talcum powder products, not the talc used in
- pleurodesis, not talc on surgical gloves.
- 8 Having said that, I think it's an important
- piece of information to know that talc on
   surgical gloves can cause a granulomatous
- <sup>21</sup> reaction, because that is further evidence for
- <sup>22</sup> plausibility that talcum powder products --
- 23 they're called talcum powder products, so, again,
- <sup>24</sup> it's sort of an assumption. It doesn't really
- <sup>5</sup> matter to me what's in there, but my assumption

- 1 place into the perineum. We don't know how much
- <sup>2</sup> of that product is getting to the ovary. We know
- <sup>3</sup> that it can get to the ovary because we've seen
- <sup>4</sup> talc in the ovary. But where -- it's extremely
- <sup>5</sup> difficult in this type of situation, when women
- use the product differently, to know what the
   dose -- what a single dose is.
- 8 Now, if you're talking long-term, frequent
- <sup>9</sup> use of talcum powder products, of course, the
- exposure is going to be greater than a single use
- 11 of that product.
- But are we ever going to know what one dose
- 13 of talcum powder product is? I don't think we're
- 14 going to be able to say that and how much of one
- <sup>15</sup> dose reaches the ovary.
- But, certainly, again, with -- over time,
- <sup>17</sup> increased frequency and duration, it's -- you
- 18 know, more of that product is going to reach the
- 19 ovary.
- Q. So going back to the discussion we had
- 21 earlier about surgical glove talc, do you know of
- 22 any literature that links exposure to talcum
- 23 powder -- pharmaceutical-grade talcum powder from
- <sup>24</sup> surgical gloves to any kind of cancer?
- A. I did not opine on surgical glove talc

- 1 is that whatever -- the talc or whatever is in
- <sup>2</sup> that product is causing the -- a chronic
- <sup>3</sup> inflammation. And so it's part -- it's a piece
- <sup>4</sup> of evidence for the plausibility.
- Q. So are you not aware of any studies,
- <sup>6</sup> based on the review that you did conduct, that
- 7 link surgical glove talcum powder with the
- 8 development of any cancer?
- 9 MR. ROTMAN: Objection.
- A. So I'm not sure how you could do that.
- If you're looking at patients who -- I think that
- would be a very difficult study to design.
  - If you're looking at women -- if you're
- 4 doing a case-control study -- I'm just
- thinking -- and you're looking at patients who
- 16 have been diagnosed with ovarian cancer who have,
- at any time, had surgery during the time period
- 18 that talc was used on surgical gloves, I think
- that would be a difficult study.
- Q. My question to you was --
- MR. KLATT: Objection. Nonresponsive.
  - Q. My question to you was: Are you aware
- of any studies or literature that link
- <sup>24</sup> talc-dusted surgical gloves to the development of
- 5 any kind of cancer?

Page 152 Page 150 1 MR. ROTMAN: Objection. <sup>1</sup> could be helpful information to my general 2 THE WITNESS: My thing is not --<sup>2</sup> causation opinion. So it's possible that I did. 3 Q. Is it in your report or cited in any of MR. ROTMAN: There's a button you can your reference lists? 4 push. 5 A. Again, I can look through my whole THE WITNESS: Oh, "follow." 6 <sup>6</sup> reference list. It's the same answer. Off the MR. ROTMAN: Do you see the button that's flashing on the right-hand -top of my head, I don't know the answer to that. Q. Do you know of any studies or any data THE WITNESS: Yeah. 9 that link foreign-body granulomas to the MR. ROTMAN: -- side? If you hit that, development of any kind of cancer? it should go to the bottom. 11 THE WITNESS: Okay. I see. Yup. A. Well, we know that asbestos can cause a 12 MS. AHERN: And I'll withdraw that, granulomatous reaction and asbestos is certainly <sup>13</sup> because there's -- the question asked first was, associated with mesothelioma and lung cancer. <sup>14</sup> I think, better. I slightly modified it on Q. Are there other biologic properties of <sup>15</sup> accident. 15 asbestos that contribute to its carcinogenicity? <sup>16</sup> BY MS. AHERN: 16 A. It can provoke a reactive oxygen species inflammatory response. Q. Are you aware of any studies, based on your review, that link surgical glove talcum Q. Can it disrupt DNA? 19 powder with the development of any kind of A. It can based on that mechanism, yes. 20 cancer? 20 Q. Have you seen any studies or data 21 suggesting that talcum powder can do those And, Doctor, to be clear, I'm only <sup>22</sup> interested in whether you know of a study, not 22 things? 23 whether one could be conducted. A. I've seen studies that show that talcum A. Off the top of my head, it's possible powder can increase production of reactive oxygen 25 that one exists, but I can't come up with one off species and can change gene expression in Page 151 Page 153 1 mesothelial cells. So, yes, I mean -- let me go 1 the top of my head. Q. Do you know of any data linking <sup>2</sup> back to your question. <sup>3</sup> surgical glove talcum powder with the development So I would say, yes, there are studies that 4 of any cancer? 4 show talc can cause the production of reactive 5 MR. ROTMAN: Objection. <sup>5</sup> oxygen species and reactive nitrogen species, 6 A. It would be my same answer. which can disrupt DNA, similar to asbestos. 7 Q. That you don't know, but there might Q. How do reactive oxygen and nitrogen 8 be? species disrupt DNA similar to asbestos? 9 A. Sitting here right now, I can't come up A. Well, it's the reactive oxygen species with a specific study that evaluated ovarian -- it's part of this feedback loop with -- what's 11 cancer patients who have had surgery with talcum the word I'm looking for? -- tumor factors like 12 COX and TNF alpha. It's related to those types powder gloves. 13 Q. Any cancer. Not ovarian cancer, any of expressions and an inflammatory response. 14 cancer. Q. Are you relying on cell studies? 15 15 A. Similar. Sitting here right now, I MR. ROTMAN: Objection.

<sup>16</sup> cannot think of one off the top of my head.

Q. And wouldn't that have been something 18 you think you would have picked up in your 19 review?

A. It's possible that I did. I just said 21 I can't think of it off the top of my head. It's 22 possible that I did at some point.

23 But my -- and, again, I tried to make every

<sup>24</sup> effort to be able to identify studies and

25 literature and evidence that were relevant or

A. I have looked at cell studies. The

Buz'Zard study is one, and I know Saed has done a lot with myeloperoxidase and ovarian cells. He

recently came out with a paper.

So it's, again, a piece of information towards the plausibility arm of my general causation opinion.

23 Q. Have you seen any studies in animals or in humans that have linked the specific enzymes that Dr. Saed has evaluated in cell studies to

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the development of ovarian cancer?

- A. So there have been some studies that
- <sup>3</sup> have looked at anti-inflammatory drugs, aspirin
- <sup>4</sup> and NSAIDs in particular.
- The data on NSAIDs has been less consistent,
- <sup>6</sup> but the data on aspirin has been consistent, in
- <sup>7</sup> that it lowers the risk of ovarian cancer with
- <sup>8</sup> regular aspirin use.
- 9 And aspirin, one of the mechanisms of action
- <sup>10</sup> is on the cyclooxygenase expression, which is
- 11 similar to the cyclooxygenase expression seen in
- 12 some of the in vitro studies.
- Q. So my question was: Have you seen any
- 14 studies in animals or in humans that have linked
- <sup>15</sup> specific enzymes that Dr. Saed has evaluated in
- <sup>16</sup> his cell studies to the development of ovarian
- <sup>17</sup> cancer?
- MR. ROTMAN: Objection.
- Q. Are you relying, then, on epidemiologic
- <sup>20</sup> studies looking at NSAID and aspirin use?
- MR. ROTMAN: Objection.
- A. I'm saying that the NSAID and aspirin
- 23 use is another piece of information that -- as to
- <sup>24</sup> plausibility, mechanism -- and mechanism of
- <sup>25</sup> regulation of pathways that can result in
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- $^{\, 1} \,$  reactive oxygen species and cause an inflammatory
- <sup>2</sup> response.
- 3 MR. KLATT: Objection. Nonresponsive.
- 4 MS. AHERN: Same.
- <sup>5</sup> Q. Let's go back to that. We'll finish up <sup>6</sup> this Exhibit 11.
- What was the next page, if any, the last
- 8 page in your photocopy?
- 9 A. Okay. So this is Page 1216 of the
- 10 fourth edition, if I am correct. Give me one
- 11 second while I find it.
- Okay. So the reason why Page 1216 is there
- 13 is because it starts the section on ovarian
- <sup>14</sup> cancer, which then continues on to Page 1217.
- <sup>15</sup> And it says -- the last paragraph on Page 1217
- <sup>16</sup> says, "Other suggested factors affecting ovarian
- <sup>17</sup> cancer risk include talc exposure, a history of
- 18 mumps infection, and alcohol consumption. Talc
- <sup>19</sup> exposure, which has been related to an excess
- <sup>20</sup> risk of ovarian cancer in a number of
- 21 case-control studies, is of interest biologically
- 22 in that ovarian cancer is thought to arise from
- 23 the mesothelium that lines the peritoneal
- 24 cavity."

25

MR. ROTMAN: Slow it down so she can

- <sup>1</sup> get it.
- <sup>2</sup> THE WITNESS: Oh, I'm sorry.
- A. "Ovarian cancer may be analogous,
- <sup>4</sup> therefore, to plural mesothelioma, which has been
- <sup>5</sup> shown to be caused by asbestos, a chemical
- 6 similar to talc."
- Q. Is that the complete passage that
- 8 you're looking at?
- A. I believe that is why I had highlighted
- 0 that one, yes.

13

18

- Q. You'd agree that this version of
- 12 Blaustein's textbook was published in 1994?
  - A. Yes, I am aware.
  - 4 Q. Would you agree that a number of the
- 15 risk factors that have been identified here,
- there have been additional studies published on?
- <sup>17</sup> A. Yes.
  - Q. Would you agree that alcohol is a known
- <sup>9</sup> risk factor these days for ovarian cancer?
- A. I don't think that's been borne out to
- <sup>21</sup> be the case. But with talc, there's continued to
- <sup>22</sup> be several case controls and meta-analyses which
- 23 have continued to be consistent with the
- <sup>24</sup> increased risk of ovarian cancer cited in the
- 25 studies that were cited here, which I didn't
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- <sup>1</sup> actually Xerox. You have the book, so --
- Yes, I agree this was 1994, but taken into
- <sup>3</sup> context of the subsequent studies and literature
- <sup>4</sup> looking at talc and ovarian cancer, I think it's
- <sup>5</sup> still relevant.
- 6 Q. Have there been a number of updates and
- <sup>7</sup> changes to the classification of tumors since
- 8 1994?

13

- <sup>9</sup> A. Since 1994, sort of semantically. We
- 10 still have the same subtypes of ovarian cancer.
- 11 There's been a new categorization. We talked
- <sup>12</sup> about the Type 1 and Type 2 ovarian cancers.
  - So not a complete overhaul in
- categorization; I think just different ways to
- <sup>15</sup> category the same entities, let's --
  - O. Has the --
- A. -- put it that way.
- <sup>18</sup> O. Sorry.
- 19 Has the understanding of the origin of
- ovarian tumors evolved significantly since 1994?
- A. So this mentions -- we talked about
- this a little bit earlier -- this does mention
- that at this time, in 1994, there was thought
- <sup>24</sup> that ovarian cancer might arise from the
- <sup>5</sup> mesothelium. So the ovary is covered by a layer

Page 160 Page 158 <sup>1</sup> of mesothelium. That's the outer layer. And so 1 page just because it was a continuation of that. <sup>2</sup> in 1994, that was still, I would say -- this is <sup>2</sup> So, yes, I think we're done with the fourth <sup>3</sup> before my residency, a little before my time --<sup>3</sup> edition. 4 that that was the most common thought, that Sorry. I'm starting to talk fast because <sup>5</sup> that's where the ovarian cancer -- cancers are <sup>5</sup> I'm excited for lunch. MS. AHERN: We can take a break for <sup>6</sup> arising from. Now, since then we've discussed <sup>7</sup> some of the other more recent findings of the lunch, then. THE VIDEOGRAPHER: Here ends Media 3. <sup>8</sup> etiology. 9 But, anyway, I just -- I had read this a Off the record, 1:05 p.m. (Lunch recess was taken.) 10 couple of days ago and, you know, it was -- it <sup>11</sup> was a reference that I think is still relevant 11 ("Blaustein's Pathology of the 12 Female Genital Tract," Fifth Edition, 12 because of the -- the subsequent case controls 13 marked Exhibit 12.) <sup>13</sup> and meta-analyses that were done since then that 14 14 I think still make it relevant, although, again, (Excerpt of Blaustein's 15 <sup>15</sup> I -- we're not -- we're still not absolutely sure Pathology of the Female Genital Tract," <sup>16</sup> where all of these ovarian epithelial tumors are 16 Fifth Edition marked Exhibit 13.) <sup>17</sup> arising from. But we have a little more evidence 17 THE VIDEOGRAPHER: Here begins Media <sup>18</sup> than we did in 1994. No. 4 in today's deposition of Sarah Kane, M.D. 19 Q. And in 1994, the first prospective Back on the record, 1:45 p.m. 20 cohort study had not yet been published; correct? BY MS. AHERN: 21 A. I believe that is correct. O. Okay. Hi, Dr. Kane. 22 O. So we would be -- these numbers here 22 A. Hello. 23 23 in -- that are discussed for talc exposure would Q. I'm looking here at Blaustein's <sup>24</sup> be, essentially, just the retrospective case <sup>24</sup> Pathology of the Female Genital Tract, Fifth <sup>25</sup> Edition, which you brought with you here today. <sup>25</sup> controls that had been published up to that point Page 159 Page 161 <sup>1</sup> I marked it as Exhibit 12 to your deposition. <sup>1</sup> or the specific ones --<sup>2</sup> You can have it back. A. Yeah. You have the reference list of <sup>3</sup> the reference numbers 47, 69, 70, and 182. A. Okay. Q. Thank you. And inside, you brought O. Cramer? You said 59? 5 <sup>5</sup> with you a photocopy of the cover page and also A. 69. 6 O. Harlow, 92. <sup>6</sup> Page 629. I'll hand that back to you. I think 7 <sup>7</sup> there's only one copy. I've marked that as A. 70. 8 <sup>8</sup> Exhibit 13. Q. 70. Hartge. 9 9 And 83. A. Oh, okay. 10 A. And 182. 10 Q. Here you go. 11 11 Q. And Whittemore, 1988. A. Okay. 12 A. So, yes, that was before. They only 12 MR. TISI: What was the page? I'm 13 looked up until 1988. sorry. 14 Q. Okay. THE WITNESS: 629. Do you want the 15 MR. ROTMAN: Hunter, a good time to textbook back? 16 take our lunch break? It's been an hour since Q. Whichever one you'd rather actually pass back to me. Thank you. 17 our last -- since we started. 18 Can you tell us, on Page 629, what MS. AHERN: Sure. I'm sure people information you thought was relevant to your could use a bio break too.

Q. Are these the only pages that you photocopied from this book -- or in -- sorry.

Let me rephrase that.

Have we finished

25

Have we finished with the photocopy of Exhibit 11 or are there more pages?

A. I think -- I think I Xeroxed this last

review of the talc issue?
A. Yes. I believe this is under "Foreign"

22 Body." So this is diseases of the fallopian

tube. So under "Foreign Body" -- hold on one
 second. Okay. It says, "Foreign material may be

25 introduced into the tube in the course of

<sup>1</sup> gynecologic investigation, especially

- <sup>2</sup> hysteroscopic -- I can't say the word,
- <sup>3</sup> hysterosalpingo -- anyway, HPG, lubricant jelly,
- <sup>4</sup> mineral oil and starch and talc powder may cause
- <sup>5</sup> a lipoid or granulomatous salpingitis. An
- 6 intense phagocytic reaction to introduce lipid
- 7 material causes" --
- THE COURT REPORTER: Excuse me.
- <sup>9</sup> A. Sorry. I think that's basically the -- <sup>10</sup> that is the end.
- No. At the very end of the page, it says,
- 12 "Talc may cause mucosal or serosal granulomas.
- 13 Examination of all granulomas or foreign body
- <sup>14</sup> reactions under polarized light is useful in the
- 15 recognition of these processes. Other disease
- <sup>16</sup> processes in the tube such as leprosy or
- <sup>17</sup> amyloidosis are so infrequent that they are of
- 18 little clinical or pathologic significance."
- Q. How does that information inform your opinions today?
- A. So it's just another -- again, similar
- 22 to the other things that we reviewed in the other
- <sup>23</sup> edition, just another piece of evidence that talc
- <sup>24</sup> causes mucosal and serosal granulomas, and
- 25 they're talking about the fallopian tube in this
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- <sup>1</sup> chapter.
- MR. KLATT: Can I interrupt?
- 3 (Discussion off the record.)
- 4 MR. LOCKE: I'm on right now. Thanks,
- <sup>5</sup> Mike.
- <sup>6</sup> BY MS. AHERN:
- Q. And, Doctor, did you review any other
- 8 sections of Exhibit 12, Blaustein, Fifth Edition?
- 9 A. I believe I did. I think in this
- 10 edition, from what I recall, that was the -- the
- 11 reference was in the fallopian tube.
- Q. Is that what we just discussed on
- <sup>13</sup> Page 629?
- A. Yes. 629 was where talc was discussed
- 15 in the fallopian tube.
- Q. Did you see any other information in
- <sup>17</sup> any of the Blaustein texts that we reviewed today
- 18 that suggests that foreign body granulomas caused
- 19 by talc have been associated with the development
- <sup>20</sup> of ovarian cancer?
- A. Well, we saw mention of the
- <sup>22</sup> epidemiologic studies in the fourth edition that
- <sup>23</sup> we reviewed.
- Q. So other than the epidemiology, is
- 25 there any reference to pathology studies or

- <sup>1</sup> experimental studies or animal studies
- <sup>2</sup> linking talc foreign-body responses to
- <sup>3</sup> development of cancer?
  - A. From what I can recall in those
- <sup>5</sup> textbooks, I don't think they went into any more
- <sup>6</sup> detail than what I've read for you.
- Q. Okay. What else did you bring with you
- 8 today? Anything that we haven't covered other
- <sup>9</sup> than the boxes behind me?
- A. Correct. I don't think so. Mr. Rotman
- <sup>11</sup> brought a copy of my report, but that is all.
- <sup>12</sup> This -- let me look.
- All of these have been marked already.
- <sup>14</sup> Yeah.

19

21

24

- Q. All right. Doctor, you've got a copy,
- but I'm going to hand you another one. I've
- marked as Exhibit 14 a copy of your expert report
  - 8 dated November 15, 2018.
  - (Rule 26 Expert Report of Sarah
- E. Kane, M.D. marked Exhibit 14.)
  - Q. Can you review Exhibit 14 and tell us
- <sup>22</sup> if this is indeed your expert report dated
- <sup>23</sup> November 15, 2018?
  - A. Yes. This appears to be my report.
- Q. And you brought with you earlier an
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- <sup>1</sup> updated copy of your CV; correct?
- A. Yes, I did.
- O. Which we marked Exhibit 2.
- (Document entitled "References
- <sup>5</sup> Cited and Other Material and Data
- 6 Considered" marked Exhibit 15.)
- <sup>7</sup> BY MS. AHERN:
- Q. And Exhibit B to your report was
- <sup>9</sup> entitled "References Cited and Other Material and
- <sup>10</sup> Data Considered." I've marked that as Exhibit 15
- <sup>11</sup> to your deposition.
- 12 A. Okay.

- Q. Okay. And Exhibit 15 isn't paginated
- but consists of 11 pages. The first ten pages of
- <sup>15</sup> materials consist of 186 items identified by the
- indications consist of 100 feeting identified by the
- caption on the top of Page 1 as "Literature"; is
- <sup>7</sup> that correct?
- 18 A. I'm sorry. Are you talking about the
  - <sup>9</sup> "References Cited and Other Material and Data
- <sup>20</sup> Considered," Exhibit 15?
- 21 Q. Yes.
- A. Yes. There is a list of 186 literature
- <sup>23</sup> references.
- Q. And the materials listed on Page 11 are
- <sup>25</sup> identified by a caption as "Other Sources" and

- <sup>1</sup> include an additional 17 items; is that correct?
- A. Yes.
- 3 Q. Okay. So did you prepare Exhibit 15?
- 4 A. Yes. I did.
- 5 Q. Did you type this out yourself?
- 6 A. I did. Yes.
- Q. Okay. And how did you go about pulling this together?
- 9 A. I'm -- in what way?
- 10 Q. Did you keep a running list of the
- 11 citations as you went and then pull this all
- 12 together at the end of your report?
- A. Yes. So what happened is this was my
- 14 first medical expert witness report I have
- <sup>15</sup> written. And you'll notice that -- let's see,
- <sup>16</sup> all of the -- oh, I'm sorry. This doesn't
- <sup>17</sup> include the January 4th list; right?
- O. We'll get there.
- 19 A. Okay. So that's what I kind of want to
- <sup>20</sup> explain. What happened is, the reason why you
- <sup>21</sup> had a January 4th list, is because I wrote
- 22 this -- the accepted form for published
- 23 literature is listing literature that you've
- <sup>24</sup> actually cited within the body of your report,
- <sup>25</sup> and so it was my misunderstanding. I was not
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- <sup>1</sup> aware at first that you guys were going to want a
- <sup>2</sup> list of everything that I had reviewed.
- So what I tried to do is this, I think, was
- <sup>4</sup> turned in at the same time, so Exhibit 15 was
- <sup>5</sup> turned in at the same time as Exhibit 14, and it
- <sup>6</sup> has the literature that was cited within the body
- <sup>7</sup> of the report.
- And then when I realized I needed to get a
- <sup>9</sup> list together of everything, as complete a list
- 10 of everything that I thought I reviewed, I put
- 11 together the January 4th list, which was -- I had
- 12 to sort of recreate -- and I kept almost all of
- 13 those -- all of this literature in different
- 14 files.
- 15 I had to do a little bit of recreation
- <sup>16</sup> because, as I mentioned before, I lost a couple
- of hard drives during this whole process, which
- 18 was not fun. But thankfully, I was -- I had
- 19 backed up a lot of it.
- So I tried to be as complete as possible.
- 21 It is possible that there are a few things I
- <sup>22</sup> reviewed that did not make the list, which I
- <sup>23</sup> think I realized on the list that you got
- <sup>24</sup> yesterday there might have been a couple that I
- <sup>25</sup> had reviewed before, but most of that literature

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- <sup>1</sup> that you -- the list that you got yesterday is
- <sup>2</sup> stuff that I had reviewed, I believe. I have to
- <sup>3</sup> look at it.
- But my point is that list that you got
- yesterday was varied, and -- when I looked at it,
- and it was just an effort to be as complete as
- possible.
- Q. Okay. And just looking -- we'll get
- there, but just looking at Exhibit 15, which --
- the first ten pages, which are the references?
  - A. Mm-hmm.
- 12 Q. So do you define the references as the
- specific sources that you cited within the body of your report?
- 15 A. These are sources that I cited within
- the body of my report. 17 Q. And are these the sources that you rely
- on to support the opinions expressed in your
- 19 report?

11

- 20 A. So these are some of the references
- <sup>21</sup> that I used. Again, I also had reviewed the
- subsequent -- the literature and the other data
- in the subsequent lists. So I would not say this
- <sup>24</sup> is all-encompassing, but ultimately, with all the
- 25 lists you have now, I'm hoping that that is
- - <sup>1</sup> encompassing of at least all of the stuff that I
    - <sup>2</sup> considered. I wouldn't necessarily say "rely
    - <sup>3</sup> on," but at least everything that I considered.
    - Q. Okay. And that was -- my next question
    - <sup>5</sup> was: Do you differentiate between the sources
    - <sup>6</sup> cited here as references and those that you just
    - considered but weren't included as references?
    - A. Not necessarily. These are the ones
    - that ended up getting cited in the report. Now,
    - there were different drafts, which at one point
    - some of the other ones were cited, and there was

    - a little bit of changing it around, which there's
    - a couple -- I think there are a couple of
    - typographical-type errors in a couple of the
    - <sup>15</sup> references because of that.

- 16 But essentially, there isn't that much of a
- difference, I would say, except to say that this
- is the literature that I ended up specifically 19 citing.
- 20 But all of the literature that I looked at, <sup>21</sup> I considered.
  - Q. Would you say that all of the
- literature that you looked at, which would
- include your other sources here on Exhibit 15,
- your January 4, 2018, reference list, and the

<sup>1</sup> ones served yesterday, January 24th, would you <sup>2</sup> say that you relied on all of those materials?

A. No. Well, I at least reviewed those. <sup>4</sup> I would say that I considered them. I wouldn't

<sup>5</sup> necessarily say that I relied upon them.

Q. And when you consider material, what does that mean to you?

A. Well, you know, when I'm -- you can <sup>9</sup> look at my methodology, how I tried to cast as wide a net as possible with the information that <sup>11</sup> I gathered in the information stage. So I wanted

12 to have as much data, as many literature 13 references, expert reports, whatever I could kind 14 of get my hands on that might be relevant to my

<sup>15</sup> general causation report.

16 And then I'm reading through those, and <sup>17</sup> that's actually when I started my draft of the <sup>18</sup> report. It really started as sort of notes that <sup>19</sup> I took as I read the different literature <sup>20</sup> references, and I sort of built out from there.

Does that answer your question?

22 Q. I think probably so.

23 Did you collect -- did you identify all of <sup>24</sup> the materials in Exhibit 15 yourself, or were

some of these provided to you by the plaintiffs'

Page 172 <sup>1</sup> remember, I did my own literature search, read as

<sup>2</sup> much as possible, started taking my own notes.

<sup>3</sup> And then thought, as I was sort of forming my

4 opinion, thought, you know, it would be nice to

<sup>5</sup> know what the defense is saying. And, of course,

<sup>6</sup> I think at that point is when I asked, but I

don't remember specific timing.

Q. And did you specifically -- did you ask for specific defense reports or specific defense

reports related to particular expertise?

A. If I recall -- I'm looking at this 12 list -- I believe the first request was a more

general request.

Q. When you say "more general," do you mean for --

16 A. Meaning --

17 Q. -- for defense?

A. -- I didn't ask for specific names of

19 people.

18

23

20 Q. Ah.

21 A. I think at this point, I wasn't

necessarily aware of who would have been defense

experts. And so I don't remember exactly, but my

inclination is that I had asked for a more

general sort of representation.

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1 counsel?

25

A. The vast majority of them, I found <sup>3</sup> through my own literature search. Some of them

4 may have been supplied by the plaintiffs'

<sup>5</sup> attorneys. A lot of those overlapped with what I

6 had already found; the exception, of course,

<sup>7</sup> being documents on the other sources that I would

not have had access to on my own.

So I had asked for, and in forming my 10 opinion, my general causation opinion, I had 11 asked for defense expert reports so I could get a 12 sense of what the defense experts' opinions were, 13 just to get, you know, the other -- just to get <sup>14</sup> more information.

15 So that's -- so those were definitely given

<sup>16</sup> to me by plaintiffs' attorneys. 17 Q. Do you remember, timewise, did you

18 review the defense expert reports and the 19 materials in the other sources earlier on to get

<sup>20</sup> a sense of the issues in the litigation and then

<sup>21</sup> do your literature search, or the other way <sup>22</sup> around? What was the timing?

A. I don't remember exactly. I don't 23 <sup>24</sup> believe I read the -- I'm trying to think timing.

I think what I did is -- from what I

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Q. And can you identify on here which of <sup>2</sup> the other sources are from defense experts?

A. Yes. I'll try my best.

The Michael Ober expert report was provided

<sup>5</sup> by plaintiffs' counsel. The deposition of Alice

<sup>6</sup> Blount was also provided by plaintiffs' counsel.

Both of the Chodosh, his report and his trial

testimony, was provided by plaintiffs' counsel.

Samuel Cohen was provided by plaintiffs' counsel.

And also -- also, let's see, the Cramer, I

wouldn't have access to the Cramer reports on the

Byrd and Jacqueline Fox. The expert report of

13 Michael Crowley was given to me. That,

obviously, is a plaintiffs' report that was

within a day or two of turning in my report.

That was very late in the process.

John Godleski, I might have asked for by

name. Of course, he's a plaintiffs' expert.

His, I may have asked for by name because of the Cramer papers.

Q. Did you say Cramer was a plaintiff or <sup>22</sup> defense expert?

A. Cramer, I believe, was a plaintiff.

24 Q. I wasn't sure. You named him after the <sup>25</sup> defense experts. I'm sorry. I'm just going

- <sup>1</sup> through the list.
- MR. ROTMAN: The list is alphabetical,
- <sup>3</sup> so she's going down the list.
- <sup>4</sup> BY MS. AHERN:
- Q. Yeah. My question was: Which ones are
- <sup>6</sup> the defense experts?
- A. I'm sorry.
- Q. If you're done, you're done. Are there any other defense experts.
- A. Well, the John Hopkins and Julie Pier, 11 those exhibits and depositions I got from plaintiffs' counsel.
- 13 I believe that is it, looking at the list of 14 defense reports.
- 15 Q. Did you want to know what the defense experts had to say about epidemiology?
- A. I wanted -- yeah. I wanted as much 18 evidence as I could get, so --
- 19 Q. Were you aware that the defendants had <sup>20</sup> designated epidemiologists in the litigation who <sup>21</sup> had given reports and testimony?
- 22 A. I don't know if I was aware
- specifically of that.
- Q. Were you aware that the defense had <sup>25</sup> designated a number of gynecologic pathologists

- <sup>1</sup> ones that I received. Yes.
  - Q. Is there anyone on this list that's --
  - <sup>3</sup> that specifically addresses gynecologic
  - pathology?
  - A. I think it's been a long time since I
  - <sup>6</sup> read those reports, but I do remember some of

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- <sup>7</sup> those reports speaking to -- your question was on
- top. I'm just making sure.
  - Q. Sure.
- 10 A. Some -- so the gyn onc report
- <sup>11</sup> definitely went into some gynecologic pathology.
- 12 Gyn oncs are generally knowledgeable about gyn
- pathology because we work pretty closely with
- 14 them. We often show our gyn pathology, for
- <sup>15</sup> example, at multiconferences, multidisciplinary conferences.
- 17 So I vaguely remember a gyn onc one going over some gyn path stuff, but my memory is vague
- because I have not read these in probably over a
- year. I don't know exactly.
- 21 Q. Would you be interested in what the <sup>22</sup> epidemiologists that had served reports and given
- testimony in the litigation the last five years,
- what they've said?
  - MR. ROTMAN: Objection.

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<sup>1</sup> who had given reports and testimony as well?

- A. Again, I don't know if I was
- specifically aware of that. No.
- Q. Would you have, as a pathologist doing
- <sup>5</sup> an expert report on this litigation, would you
- <sup>6</sup> have been interested to know what the defense pathologists had said?
- 8 A. Well, I will take any data that I can get to try to see if it's relevant. I mean, so I
- <sup>10</sup> had asked for defense reports, and that's what I <sup>11</sup> got.
- 12
- Q. These reports, these other sources, the 13 17 items here were in response to your request, but they were chosen by the plaintiffs' counsel?
- 15 MR. ROTMAN: Objection.
- 16 A. I'm not sure how they were chosen or how -- why -- all I know is that I asked for reports, and this is what I received.
- 19 Q. And you specifically asked for defense <sup>20</sup> reports; right?
- A. I did.

25

- 22 Q. And you got Michael Beer, who is an <sup>23</sup> oncologist; Lewis Chodosh, a cancer biologist;
- and Sam Cohen, a toxicologist; correct?
  - A. That would appear, from the list, the

A. Again, I'll take whatever information

- <sup>2</sup> or data, you know, I can get that might be
- <sup>3</sup> relevant.
- Q. And do you consider expert litigation
- reports to be data?
- A. Yes. I think it's data. Q. Okay. Is it the kind of data you rely
- on in your everyday practice as a pathologist?
- A. I sort of view they're opinion reports.
- 10 They're opinion, general causation opinions, and
- <sup>11</sup> a couple of these are -- I can't remember. All
- 12 of these were general, I believe, from the <sup>13</sup> defense.
- So they're professional opinion data, and I
- would say that's similar to having a consultation with a colleague or a peer. I mean, you know, in
- my day-to-day practice, I'm certainly asking
- opinions of colleagues and different specialties
- <sup>19</sup> or my own specialty, even. Those are
- professional judgments, professional opinions,
- 21 looking at their knowledge of the literature or 22 data.
- 23 So I think it's a good analogy; looking at
- general causation, professional opinions, is
- <sup>25</sup> similar to kind of getting a colleague's opinion.

Q. But this is the first time you've relied on litigation reports to inform your own opinions; correct?

A. Well, again, I don't know if I would use the word "rely." I certainly considered them, you know. But, again, I think it's very similar to asking a colleague in my daily practice for an opinion on something.

<sup>9</sup> Q. And, Doctor, looking at 186 references <sup>10</sup> that are cited in Exhibit 15.

Did you review each one of these carefully and thoroughly?

A. I reviewed each one of them, some of them probably more thoroughly than others, depending on what I was looking for; but yes, I reviewed all of them.

Q. And do you know whether or not the boxes, the four boxes that are sitting behind me, do those include these 186 references on Exhibit 15?

MR. TISI: Let me see if I can help you out.

MS. AHERN: Sure. Go ahead.

MR. TISI: My understanding is they do.

MS. AHERN: That's the 186?

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MR. TISI: That would be the references in the report. It would not be, to my -- I

<sup>3</sup> haven't cracked the boxes, so I can only assume

<sup>4</sup> from past prologue that the information

considered is not in those boxes. They may be,
 but the information relied on that is cited in

7 the report are.

MS. AHERN: Okay. So other sources
here that are not cited specifically, well, they
may be -
MR. TISI: I don't know for example --

MR. TISI: I don't know, for example -well, maybe we can open them up. But I don't
know, for example, if the expert reports and
depositions are in the -- in there. If they're
cited, then they're probably in there. If
they're not cited --

THE WITNESS: I'm not sure because -
18 I'm not sure I cited these in my report because

19 they weren't necessarily reliance. It was more

20 data.

But I thought at the time that I should list what -- because these aren't publicly -- I don't believe any of these are publicly

available, what is on this list, so I felt like I
 should list them.

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But I don't believe I -- well, I might

But I don't believe I -- well, I might have referenced the Longo.

<sup>3</sup> BY MS. AHERN:

Q. Page 5. I think if you look at Page 5 of your report, you reference Dr. Blount --

6 A. Yes.

Q. -- Dr. Crowley, Longo, Rigler,

8 Hopkins --

A. Yes.

<sup>10</sup> Q. -- Pier?

A. Yes. Looking back at the list, you're absolutely correct. I did.

Q. Do you think, as you sit here, that those are --

MR. TISI: I can look at them if it makes your life easier. I'm happy to do it.

But I do think -- Mike is back there looking. I'm thinking that those are the actual, relied-on referenced materials, not the materials considered, which was a separate list.

MS. AHERN: That's the January 4th, and we're going to get to that one.

MR. TISI: No. it's in the back of the report. Maybe I'm wrong.

MS. AHERN: There are other sources,

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<sup>1</sup> but she has apparently relied on them --

MR. TISI: That's fine.

3 MS. AHERN: -- to some extent in

<sup>4</sup> performing reviews about fragrances and asbestos.

<sup>5</sup> BY MS. AHERN:

Q. Is that right, Doctor?

A. Dr. Crowley's report and Dr. Longo's

<sup>8</sup> report, yes. I --

9 Q. And what about Dr. Hopkins and Pier?

A. Yes. I don't believe I read their

<sup>11</sup> entire depositions. I know I had seen the

12 exhibits from the depositions, and I think

<sup>-3</sup> part -- I listed it here, so I must have at some

14 point.

MS. AHERN: Okay. So let's put 15 over here, and let's move on to the next one.

17 (Document entitled "Additional

<sup>18</sup> Material Considered" marked Exhibit 16.)

<sup>9</sup> BY MS. AHERN:

Q. Okay. Doctor, I'm handing you what's been marked as Exhibit 16 to your deposition.

Can you take a look at Exhibit 16 and tell

23 us what that is?

A. Yes. So this is a combination. So once I realized that I needed to give you all a

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list of -- as complete a list as I could -- I'm

- <sup>2</sup> not going to say this is a complete list -- and,
- <sup>3</sup> of course, you have another list that you just
- <sup>4</sup> got, but I tried to be as complete as I could in
- <sup>5</sup> recreating the literature and other reports that
- <sup>6</sup> I had considered.
- <sup>7</sup> So these are ones that, to my recollection,
- 8 I didn't specifically cite or were not
- <sup>9</sup> available -- I mean, obviously, I have some of
- 10 the plaintiffs' expert reports that weren't
- <sup>11</sup> available to me until after I had written and
- 12 submitted my report. So some of these were
- <sup>13</sup> available to me only after -- and the Health
- <sup>14</sup> Canada came out after my report.
- So these are a combination of things I
- <sup>16</sup> reviewed subsequent to November 15th and stuff
- <sup>17</sup> that I had reviewed prior to that but had not
- 18 specifically cited and recreated the list.
- Q. Okay. And just for the record, this
- <sup>20</sup> is -- Exhibit 16 is a four-page document. It's
- 21 not paginated, but it has 96 items identified as
- <sup>22</sup> "Additional Materials Considered," so -- served
- <sup>23</sup> on January 4, 2018.
- <sup>24</sup> Can you identify, as you look through these
- 25 items on Exhibit 16, which of those you reviewed

A. No.

Q. And are there some materials on

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- <sup>3</sup> Exhibit 16 that were provided to you or
- <sup>4</sup> identified for you by the plaintiffs other
- <sup>5</sup> than -- and I'm not talking about the litigation
- <sup>6</sup> materials, but the articles?
- A. Again, there might have been some that
   overlapped with what I had already found. I'm
- <sup>9</sup> looking.

I believe the April 2014 FDA letter may -although that might have been available on the
internet. I might have come across that on my
own first.

No. I believe the vast majority of this

15 stuff was stuff that I -- other than those

<sup>16</sup> reports was stuff that I had independently

<sup>17</sup> already found. That's the only one that is

18 ringing a bell as a possibility, but I also seem

<sup>19</sup> to remember finding it on the internet.

Q. Okay. And are any of these materials, materials that you explicitly rely on or, excuse

<sup>22</sup> me, are any of the materials on Exhibit 16

<sup>23</sup> materials that you rely on to support your

4 opinions?

A. Again, it's all data that I considered.

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- $^{1}\,$  prior to the submission of your report and which
- <sup>2</sup> ones you reviewed after?
- A. I can do the best that I can. My
- <sup>4</sup> memory might be a little -- and I have to jog my
- <sup>5</sup> memory a little bit on some of them.
- 6 Clearly, the expert reports that were
- <sup>7</sup> dated -- the plaintiff expert reports that were
- 8 dated after my report, I had not seen --
- <sup>9</sup> Q. Mm-hmm.
- <sup>10</sup> A. -- prior.
- And, again, the Health Canada came out
- <sup>12</sup> afterwards, so that was not available when I
- 13 submitted my report. The majority of the rest of
- 14 the literature, I had read prior to submitting my
- 15 report.
- Q. Okay. Had you seen any draft reports from any of the other experts designated by the
- <sup>18</sup> plaintiffs in this litigation?
- A. Not before my report. I didn't see any
- drafts. I only saw the final reports after myreport was submitted.
- Q. Okay. Did you have an opportunity to
- 23 talk with any of the other experts that were
- designated by plaintiffs prior to your reportbeing submitted?

- ich 1 I didn't specifically cite them, but there's
  - <sup>2</sup> certainly pieces of information that helped me
  - <sup>3</sup> come to my conclusion.
  - Q. And you prepared Exhibit 16, didn'tyou?
  - A. Yes.
  - <sup>7</sup> Q. And do you remember when you prepared
  - 8 it?

- <sup>9</sup> A. Very shortly before you received it.
- 10 So it would have been -- you received it
- 11 January 4th?
  - Q. Mm-hmm.
- <sup>3</sup> A. I think I -- it was only -- I don't
- 14 remember exactly, but it wasn't very long before
- 15 that that I put it all together, after
- <sup>16</sup> recreating -- trying to recreate as best I could
- <sup>17</sup> the list of literature that I had reviewed.
- Q. And did you carefully and completely
- review all of the information in Exhibit 16?
   A. Again, I reviewed all of it. Some of
- it was more relevant than others, likely, so --
- Q. Okay. Obviously, anything that you
- received after your report is information you
- would not have relied on to form your opinions in

<sup>1</sup> this case; correct?

- A. No. It's more information for my -- my opinion hasn't changed since I wrote my report.
- <sup>4</sup> In fact, I know we've talked about Health Canada
- <sup>5</sup> a little bit, but that was pretty interesting to
- <sup>6</sup> see that report because their methodology was
- <sup>7</sup> very similar to mine, and they did a Bradford
- <sup>8</sup> Hill analysis, and they looked at a lot of the
- <sup>9</sup> same literature and came to the same conclusion.
- So that definitely was supportive evidence,
- I think -- not I think; it is -- of my opinion.
   Q. And, Doctor, I only have one copy of
- 13 this. It's "Additional Materials to Sarah Kane"
- <sup>14</sup> that were served last night or yesterday
- <sup>15</sup> afternoon, January 24th.
- 16 (Document entitled "Additional
- Materials to Dr. Sarah Kane" marked Exhibit
- <sup>18</sup> 17.)
- <sup>19</sup> BY MS. AHERN:
- Q. First of all, can you take a look at
- 21 that?
- Have you seen it before?
- A. Yes. Yes. I have.
- Q. Did you prepare that?
- A. I did. I had listed -- there are a

- I think that covers most of them.
- Q. What about the EFSA guidance on the use

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- <sup>3</sup> of weight of evidence?
  - A. Oh, yeah. That, I think, I reviewed
- <sup>5</sup> after I had submitted my report.
- 6 Q. Did that form part of the basis of your
- <sup>7</sup> opinions or your methodology?
- A. It was more of a -- it basically shows
- <sup>9</sup> that the methodology that I used is very similar
- to evidence-based medicine that we would use on a
- 11 daily basis. It kind of went through weight of
- <sup>12</sup> evidence, and it was sort of helpful to see the
- similarity of the methodology that I used coming
- 14 to my conclusion.
- Q. Was the methodology you used for
- preparing your opinions in this case and your
- 17 report in this case taken directly from the EFSA
- 18 guidance?
- <sup>19</sup> A. No. I think I just -- I saw this EFSA
- <sup>20</sup> guidance after writing my report.
- Q. Did you use any other sort of published
- <sup>22</sup> methodology on weight of the evidence when you
- <sup>23</sup> prepared your opinions?
- A. I used what we have been trained to
- use. I mean, it's evidence. It's an

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- <sup>1</sup> couple of papers that I realize I had read
- <sup>2</sup> previously and didn't -- I can tell you Purdie,
- <sup>3</sup> 1995, Keskin, 2009, I definitely reviewed while
- <sup>4</sup> preparing my report, and somehow those got off
- <sup>5</sup> the list.
- 6 The other ones, Taher wasn't available. I'm
- <sup>7</sup> trying to remember Gordon, if I had seen that.
- 8 If I had seen that before I submitted a report,
- <sup>9</sup> it was very late. It might have been after.
- The IARC heavy metals, I believe I actually
- 11 cited that in my reference list, but I was trying
- 12 to be -- it was one of these last-minute, trying
- 13 to be as complete as possible, so that actually
- 14 might be a repeat.
- The website, I had reviewed prior to turning
- <sup>16</sup> in my report. And the Longo supplemental report,
- <sup>17</sup> obviously, wasn't available until January. Same
- 10 total 1 to TEL 111
- <sup>18</sup> with the depositions. Those weren't available
- <sup>19</sup> until after they were done.
- The Kurman defense report, I asked for
- <sup>21</sup> recently when I realized that Kurman was a
- 22 listed -- a named expert witness, which is also
- <sup>23</sup> why I went through my copies of my old textbooks
- <sup>24</sup> and my partner's old textbooks. So that, I asked
- <sup>25</sup> for specifically.

- 1 evidence-based medicine model of methodology and
- <sup>2</sup> coming to conclusions. So it's -- I tried to do
- 3 as thorough as possible description of my
- <sup>4</sup> methodology, which we can refer to in my report
- <sup>5</sup> if you'd like.
- Q. What about the J&J Science Day
- <sup>7</sup> presentation?
- A. That --
- 9 MR. ROTMAN: Objection. Is there a 10 question?
- MS. AHERN: I'm about to get there if you'd let me finish my question.
- MR. ROTMAN: I thought you were.
- 14 Sorry.
- MS. AHERN: You might just hold off.
- <sup>16</sup> BY MS. AHERN:
- Q. What about the J&J Science Day
- $^{\mbox{\scriptsize 18}}$  presentation? Is that something that you
- 19 reviewed?

- A. I reviewed that very quickly, and I
- only received that maybe a week ago. It was veryrecently.
  - Q. Did you request that information?
- A. I think, from what I remember, it was
- <sup>25</sup> part of asking for more sort of defense side of

- <sup>1</sup> the story; what, you know, your experts might
- <sup>2</sup> have been saying; what kind of -- you know, I was
- 3 trying to figure out how somebody who had looked
- 4 at the same body of evidence that I did can come
- 5 to a different conclusion, so it was part of sort 6 of that request.
- I think I probably got it after I requested
- 8 Kurman's defense report from a prior litigation,
- if memory serves me correctly.
- 10 Q. You would agree that a very large part, 11 not just volume, but a very large part of your
- 12 report and your opinions in this case are related
- 13 to the observational epidemiology on talc and
- <sup>14</sup> ovarian cancer; is that correct?
- 15 A. Well, I think that epidemiology
- 16 literature is extremely compelling. You have
- 17 30 case-control studies over different periods of
- 18 time in different populations that have come to
- 19 the same -- same ballpark relative risk, I would
- 20 say, 1.3 to 1.4.
- 21 Now, not all of those have been
- 22 statistically significant, but some of those
- 23 studies were smaller studies, and so that tends
- 24 to decrease the power of the study and your
- 25 confidence intervals will be wider.
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- But I thought the epi data was really
- <sup>2</sup> compelling. And often in causation, the epi data
- 3 sort of leads the way in paving a path to
- 4 figuring out causation.
- A perfect example is tobacco. You know, the
- <sup>6</sup> Surgeon General issued his report in the 1960s
- <sup>7</sup> about tobacco before they had any mechanism for
- 8 tobacco causing -- so that was a perfect example
- of the epi data leading to causation.
- 10 So it's true, a lot of the studies looking
- 11 at talcum powder products and ovarian cancer are
- 12 epidemiology studies, but they're extremely
- 13 informative in that they are very consistent in
- 14 their findings. And, again, different authors,
- 15 different populations, different countries.
- 16 And there's also the cohort. So I went
- 17 through the cohort studies. The cohort studies,
- 18 some of them showed an association with serous
- 19 invasive carcinoma, but the cohort studies didn't
- 20 tend to find, other than that, a statistically
- 21 significant increased risk, although some of them <sup>22</sup> did find increased risk.
- 23 But we can talk about cohort studies versus 24 case-control studies if you want, but I think the
- 25 difficulty with cohort studies is ovarian cancer

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- 1 is such a rare disease, and you're sort of, you
- 2 know, rolling the dice when you enroll patients
- 3 as to whether or not they're going to end up with
- <sup>4</sup> a disease at the end that you want to study.
- So you're sort of -- and these cohorts are
- 6 also designed for multiple endpoints and multiple
- diseases. They weren't just looking, most of
- them -- I believe the sister -- well, the sister
- study -- anyway, we can pull it out if I have to,
- but my point is the cohort studies are designed
- for multiple different things, especially the
- Nurses' Health Study.
- 13 And so it's a difficult type of study to
- design with a very rare disease. And I think
- 15 that's where the case-control studies are
- 16 important because you can start with the disease
- and work backwards, and so you can have an easier
- time getting cases.
- Q. Did you find it interesting or odd that 19
- you were provided with a number of defense expert
- 21 reports, but not a single one of them related to
- 22 the epidemiology specifically from an
- epidemiologist?

24

- A. Well, you know, again, I don't pretend
- 25 to know why I was sent what I was sent. I just
- <sup>1</sup> know that I asked for reports, and I got what I

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- <sup>2</sup> got. So I have no idea what the process was in <sup>3</sup> deciding what I received; if there was even a
- 4 decision. For all I know, it's just what they
- <sup>5</sup> had readily available.
  - Sorry. What is the question?
  - Q. Well, let me ask another question.
- 7
- MR. ROTMAN: Let her finish the answer
- <sup>9</sup> because you can read -- she can go back and read 10 from the realtime what the question was and see
  - if she's done.
- 12 A. So I guess I don't know if there was
- 13 thinking -- what the thinking was or if there was any. But also I can say that the epi data -- I
- 15 knew that by that point that the epi data was
- <sup>16</sup> consistent by the time I -- I think that was the
- first literature that I was looking at, and so I
- knew that it was consistent.
- 19 So it's -- anyway, I don't really -- I don't
- know is the answer, the short answer. 21 The long answer, the short answer is I don't
- 22 know why I got what I did. I just did.
- 23 Q. Okay. And you've seen the designations <sup>24</sup> in this case from November of 2017 in which you
- <sup>25</sup> were listed formally and publicly as an expert

Page 194 Page 196 <sup>1</sup> for the MDL? Have you seen that document? 1 MR. TISI: That's fine. 2 A. I'm not sure that I have, actually. 2 MS. AHERN: Absolutely. O. Were you aware that in November of 3 I have the date as November 6, 2017. 4 2017, you were listed on a court document as an 4 MR. TISI: You are exactly -- well, it <sup>5</sup> expert for the plaintiffs in the MDL litigation? is what it is. MR. ROTMAN: Objection. MS. AHERN: Okay. Either way. 7 A. I don't know the timing or I don't BY MS. AHERN: think I saw the document, so I... Q. Okay. Doctor, if you turn to -- if you 9 turn to Page 8, the bottom of Page 8, do you see ("The Plaintiffs' Steering vour name? 10 Committee's Initial Designation and 11 Disclosure of Non-case Specific Expert 11 A. Yes. Witnesses" marked Exhibit 18.) 12 12 Q. Okay. And did you -- go ahead and 13 review the text here associated with your name 13 BY MS. AHERN: 14 Q. Okay. I'm marking Exhibit 18 to your and designation. <sup>15</sup> deposition. Do you see this document, 15 (Witness complies.) <sup>16</sup> Exhibit 18, is entitled "Plaintiff Steering 16 Q. Just let me know when you're finished. 17 Committee's Initial Designation and Disclosure of 17 A. I'm finished reading my blurb. I'm <sup>18</sup> Non-case Specific Expert Witnesses"? just looking... 19 19 A. Okav. O. Sure. 20 20 Q. And if you turn to -- first of all, A. Okay. let's see. Unfortunately, I can't find the date 21 Q. Were you aware in November of 2017 that on that, and I apologize. you had been publicly disclosed as an expert on 23 MR. TISI: It's January, if I'm not behalf of plaintiffs in the MDL? mistaken. I think it was mid-January of 2017. MR. TISI: Okay. That's -- and you do MS. AHERN: Is that what it is? kind of need to know the context in which this Page 195 Page 197 MR. TISI: Yeah. And, Counsel, since I <sup>1</sup> was done. <sup>2</sup> was involved in this process, if you don't mind MS. AHERN: I'm just asking if she was <sup>3</sup> if I place an objection here. <sup>3</sup> aware she was publicly -- she was already MS. AHERN: Sure. <sup>4</sup> retained at that point. MR. TISI: As you may not know, during MR. TISI: She was retained, but there <sup>6</sup> the status conference where this was ordered -- I <sup>6</sup> was no -- the judge was very clear when she <sup>7</sup> don't have the transcript in front of me -- it <sup>7</sup> ordered that this be done. She understood that <sup>8</sup> was intended to be an interim -- I don't know this was not a disclosure of experts. So when you ask the question "You <sup>9</sup> what the questions are going to be, but it was understand you were being identified as an expert 10 intended to be an interim disclosure to help <sup>11</sup> guide the legal process for identifying issues at that time," she would have no way of knowing 12 that would be involved in Judge Wolfson looking that because we didn't know it. 13 <sup>13</sup> at the science. MR. KLATT: Chris, you've got to limit It was never -- I don't know -- again, your objection. 15 15 not knowing what your questions are, I don't even MR. TISI: No. But it's unfair 16 think it would be intended to be used as an 16 because -expert -- as an exhibit in a deposition. 17 17 MR. KLATT: You're coaching the But, you know, whatever your questions 18 witness. You're telling her the whole story. are, we would like to reserve that because --MR. TISI: It's a true story. Why 19 20 don't we ask her to leave, and we'll put it on MS. AHERN: Sure. MR. TISI: -- this was intended to be the record. I have no problem with that. <sup>22</sup> a -- more of an informative document than 22 MR. KLATT: All right. 23 MR. TISI: We can ask her to leave, and <sup>23</sup> anything else. 24 MS. AHERN: Okay. Your objection is we can put it on the record. 25 25 noted. MR. KLATT: Let's do that.

Page 198 Page 200 1 MR. ROTMAN: Go get a cookie. MR. TISI: She was probably not, I 2 MS. AHERN: Sorry, doctor. <sup>2</sup> mean, what she was aware of when she had been 3 <sup>3</sup> retained. (Witness exited) 4 MS. AHERN: My questions on this are MS. AHERN: Did she agree to be <sup>5</sup> fairly limited to the time period that she was disclosed as an expert? retained, time period she was intending to be an MR. TISI: She agreed to be retained. She was disclosed as an expert when she reached expert, that sort of thing --MR. TISI: Yeah. her conclusions in the case. 9 MS. AHERN: -- and the subject matter And so what the Court was requiring us that she is being designated for. to do was to give us a broad brush, and she was 11 MR. TISI: Yeah. But, you see, the <sup>11</sup> very clear. I remember standing in court, and 12 she said, "Look, some of these may fall off your 12 issue in the case -- and the reason why this was 13 list. Some of these may -- we may have people <sup>13</sup> a tricky issue for the judge and -- well, I won't 14 speak for the judge, but for us when we disclosed 14 that might be added, but I want a snapshot in 15 this was because we didn't know -- we didn't have time as to what I'm dealing with in terms of" --<sup>16</sup> expert reports. We didn't even have opinions 16 MR. KLATT: We don't need to waste time <sup>17</sup> yet. on the record on this. 18 MR. TISI: We can go off the record if So this was being done in a way that said, "Okay, Judge, she wants to know, A, are you want. I just don't want to be -- use this as 20 there new and different witnesses that were going an unfair -- you know, none of your questions 21 to be designated that were different than what have been unfair up until now. 22 was designated in the state court?" But to take this document and to 23 23 suggest in some fashion -- and I don't know what MS. AHERN: I do recall this, yes. 24 MR. TISI: The second issue, she was you're going to do with it. Maybe we just need 25 to wait and see. <sup>25</sup> very clear that she understood that there was a Page 199 Page 201 <sup>1</sup> lot of discovery that needed to be done, But I think this is -- I don't think <sup>2</sup> documents to be reviewed, science that was going <sup>2</sup> anyone ever intended that this document would be <sup>3</sup> to come out. So she was pretty clear that this 3 used as an exhibit in a deposition of one of 4 was more informative than anything else. 4 these witnesses. I don't think the court And so when you ask her a question 5 intended that to be the case, just like she --6 about -- when you ask her questions, "You know <sup>6</sup> when she ordered the Tardek report --<sup>7</sup> when this document was disclosed when you were informational only. <sup>8</sup> identified as an expert," you know, it implies MR. KLATT: Are we off the record? <sup>9</sup> that she had agreed to be -- you know, what her <sup>9</sup> We're just going on here. Let's go off the <sup>10</sup> opinions actually were at that time. 10 record. She -- I can tell you that these 11 11 MR. TISI: Yeah. 12 reports were done over a period of time. So it's 12 THE VIDEOGRAPHER: Off the record, 13 misleading, and it really is an unfair thing to 13 2:38 p.m. <sup>14</sup> do to a witness because this was a court request (A recess was taken.) 15 15 having nothing to do with her opinions or her THE VIDEOGRAPHER: Back on the record, <sup>16</sup> expert report. 16 2:42 p.m. 17 17 MS. AHERN: Okay. (Witness returns) 18 MR. TISI: Do you understand where I'm 18 BY MS. AHERN: 19 coming from? Q. Okay. Doctor, I've just shown you a 20 copy of some early designations that were 20 MS. AHERN: I understand where you're 21 coming from. submitted in the talc MDL, and you saw your name 22 Here is my question to you: Did Dr. --22 listed as one of the people who was being <sup>23</sup> was Dr. Kane not aware that you were going to considered as an expert; correct? <sup>24</sup> designate her or that you had at least publicly 24 A. My name is in this document. Yes. 25 <sup>25</sup> disclosed her to the Court? Q. Okay. Is there any -- do you have any

- <sup>1</sup> issues with the description of the testimony that <sup>2</sup> you were going to offer to give?
- A. I believe that to be accurate.
- Q. Okay. And you had been working on your <sup>5</sup> report at this point since May of 2017; correct?
- A. I started in May. "Writing the report"
- <sup>7</sup> is a very loose description. What I was -- what
- 8 I started, as I mentioned before, was I started
- <sup>9</sup> to review literature. I sort of took notes. So
- <sup>10</sup> I sort of counted that as writing. So I started
- 11 that process in May.
- 12 Q. Okay. And the only thing I was going
- 13 to ask you about in this report is, as you look
- 14 through it, do you note that there are a number
- <sup>15</sup> of professional epidemiologists that have been
- 16 listed in this report on behalf of plaintiffs?
- A. I'd have to go through the list. I
- <sup>18</sup> actually, even though I did have access to
- 19 several final reports, after I had submitted my
- <sup>20</sup> report, I don't remember who was what specialty,
- <sup>21</sup> what field, for the majority of them.
- 22 Q. Well, how about this question: Of the
- 23 experts -- are you aware of which experts have
- <sup>24</sup> submitted reports on behalf of the plaintiffs?
  - A. I would need to look at the list that I

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- <sup>1</sup> asked me if I would be willing to do an extensive
- <sup>2</sup> review of the literature and decide what my
- <sup>3</sup> opinion would be on talcum powder products
- causing ovarian cancer.
- Q. Did you ask them or discuss with them
- <sup>6</sup> what your role would be in terms of your specific
- area of expertise in anatomic pathology?
- A. I did not specifically talk to them
- about that because I know that I'm a gynecologic
- pathologist, so I thought that would be my area
- where I weigh in on my opinion.
- 12 Q. And where in your report specifically
- do you address your expertise in gynecologic
- pathology, anatomic pathology?
  - A. I list it in the beginning of my
- report, I think. I talk about -- I talk about my
- background.
  - Is that what you mean?
- 19 Q. I mean more in terms of the opinions
- 20 that you're giving being informed by your
- expertise in anatomic pathology.
- A. Well, again, I'm an expert in
- gynecologic pathology, and the question is about
- a causation of ovarian cancer, so certainly that
- <sup>25</sup> falls into my area of expertise.

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- <sup>1</sup> reviewed, which I think is all of the ones that
- <sup>2</sup> were submitted, and compare it to this list.
- I mean, I know Jack Siemiatycki is an
- <sup>4</sup> epidemiologist, off the top of my head.
- <sup>5</sup> Dr. Singh, I believe, is an epidemiologist.
- But without going through the list and sort
- <sup>7</sup> of jogging my memory as to the reports, I skimmed
- a lot of these reports.
- Q. Okay. And I guess the point is: Are
- you aware, as we sit here today, that the
- 11 plaintiffs have designated a number of
- <sup>12</sup> epidemiologists in this MDL litigation who have
- 13 given reports and/or testimony at this point on
- 14 the topic of epidemiology, talc and ovarian
- 15 cancer?

16

25

- A. I am aware that they have
- epidemiologists that have submitted reports for
- 18 this MDL.
- 19 Q. Okay. And specifically, if you can
- 20 think back to your initial contact with
- 21 plaintiffs' counsel when you were asked to get
- <sup>22</sup> involved in the litigation, what specifically
- <sup>23</sup> were you asked to do, or what was your
- <sup>24</sup> understanding of what your role would be?
  - A. Yeah. My understanding was they had

- Page 205 Q. And do you specifically address in
- <sup>2</sup> terms of anatomic pathology or ovarian cancer
- pathogenesis the question of talc and ovarian
- cancer?

23

24

- A. I think that goes to the plausibility,
- the mechanisms, as part of it.
- Q. And which particular mechanisms are
- informed by the discipline of anatomic pathology
- and gynecologic pathology?
  - A. Well, I think pathologists, anatomical
- and clinical pathologists, have training in
- inflammation and immunology and certainly
- epidemiology, looking at epidemiologic studies.
- I think all of it is within the realm of
- gynecologic pathology.
- 16 Q. Did you discuss anywhere specifically
- in your report the biology of foreign body
- reactions and granulomas as a part of the
- biologic plausibility for exposure?
- 20 A. Let me refer to my report. I
- definitely talk about inflammation. I can do a word search for granulomas, if you would like.
  - Q. Do you talk about inflammation --
    - MR. ROTMAN: Would you like --
    - Q. -- in the context of anatomic

Page 206 Page 208 1 pathology? <sup>1</sup> any other portions of your report that directly 2 MR. ROTMAN: Would you like to do that? <sup>2</sup> address ovarian cancer pathogenesis from a pathology standpoint," and --<sup>3</sup> Because I can get your report up electronically. MS. AHERN: I know where she's A. So my answer is I did the work, but I <sup>5</sup> mentioned granulomas. I already know. I'm just <sup>5</sup> can't discuss it because of attorney work product asking her if she knows. issues. 7 MR. ROTMAN: So she wants to find it Q. Okay. MR. ROTMAN: You can -- she can -- you quickly. 9 MS. AHERN: You can give her your can ask her questions about it. computer and let her search. MS. AHERN: Sure. 10 11 MR. ROTMAN: Okay. That's what I was 11 MR. ROTMAN: But she's -- as to what is 12 asking. 12 in the report or not in the report, that's the work product piece. 13 BY MS. AHERN: 14 Q. Do you cite any publications describing 14 MS. AHERN: That's kind of all the 15 the biology of granulomas? 15 questions. 16 A. I know some of the literature talks 16 MR. ROTMAN: Ask her about the science. 17 <sup>17</sup> about granulomatous inflammation, discusses MS. AHERN: I'll ask, and you can granulomatous inflammation. 18 object. 19 MR. ROTMAN: If you want to search, do 19 MR. KLATT: Find out what is in or is 20 you know how to do it on this computer? Edit, 20 not in the report. 21 Find, then you can type in a word that you want MS. AHERN: Let's pick up the 22 to search. <sup>22</sup> foundation here. 23 MR. KLATT: Is there a question? BY MS. AHERN: A. So I mention it in the animal studies, Q. Doctor, first of all, you said you did <sup>25</sup> injecting talc into the pleural spaces causes 25 the work relating to ovarian cancer pathogenesis Page 207 Page 209 <sup>1</sup> from a pathology standpoint; correct? <sup>1</sup> granulomatous response. It looks like those are <sup>2</sup> the two. A. Yes. 3 And then I cite the Mostafa 1985 paper, Q. Was it ever in your report? MR. ROTMAN: That's part of the work 4 "Foreign body granulomas in normal ovaries." I'm double-checking. It looks like in doing product objection. <sup>6</sup> a word search for granuloma, that's what is MR. KLATT: We've got to establish the facts to know whether there's a basis to assert <sup>7</sup> popping up. 8 BY MS. AHERN: the objection. 9 Q. Okay. Are there any other portions of MR. ROTMAN: You can ask the question. 10 your report that directly address ovarian cancer But in order to answer the question, you're 11 pathogenesis from a pathology standpoint? invading the domain of what is protected under 12 MR. ROTMAN: Objection. 12 the Federal Rules in terms of the drafting of 13 A. This might be attorney work product expert reports. 14 draft stuff. 14 I will object and instruct her not to 15 MR. ROTMAN: Do you want to talk to me 15 answer. 16 outside where I can understand what you're What's in the report, you have. What was in drafts of the report, you're not entitled 17 getting at? 18 18 THE WITNESS: Sure. Sure. to. 19 19 THE VIDEOGRAPHER: Off the record, So that's the problem we have. 20 2:50 p.m. MR. KLATT: She's not asking what was 21 in the report. She's asking whether it was or (A recess was taken.) 22 isn't. So we can establish if there's anything THE VIDEOGRAPHER: Back on the record, 23 2:54 p.m. to even have a dispute about.

Q. Okay. Doctor, I had asked: "Are there

24 BY MS. AHERN:

25

MR. ROTMAN: You can ask her about what

25 is in the report all you want.

Page 210 1 MS. AHERN: Well, she's already said

<sup>2</sup> there was a section on ovarian cancer

<sup>3</sup> pathogenesis from a pathology standpoint in the

report, and it was removed; correct? 5 MR. TISI: That's not what she

6 testified.

MS. AHERN: Read back.

8 MR. TISI: Why don't we read what she

said because she said the answer is:

10 "ANSWER: I did the work, but I can't 11 discuss it because of attorney work product."

12 MS. AHERN: Okay. Okay.

13 MR. TISI: She never said it was in the 14 report.

15 MS. AHERN: Thank you.

16 MR. TISI: Line 48.

BY MS. AHERN:

18 Q. When you say you "did the work," did you take any notes on any reading that you did on ovarian cancer pathogenesis?

21 A. So in writing this report, I generally did not take any notes, handwritten notes. It

was sort of a living document that I used. Q. Now, earlier, you referred several

25 times to taking notes as you were going through

<sup>1</sup> let me rephrase it.

As a gynecologic pathologist who was asked

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<sup>3</sup> to opine on ovarian cancer and talc, did you

4 assume that part of your opinions would be to

<sup>5</sup> incorporate your expertise in anatomic pathology

and gynecologic pathology? MR. ROTMAN: Wait. Wait. Wait. Wait.

Wait. MS. AHERN: I'm only concerned if she understands the question.

BY MS. AHERN:

12

Q. Do you understand the question?

13 MR. ROTMAN: No. You have to let me see if I understand the question to see if I'm going to object to it before she's allowed to 16 answer.

17 MS. AHERN: Why don't you make an objection, and we'll move on.

MR. TISI: Because he may instruct her not to answer the question.

MS. AHERN: This is not -- this is not a question that should invade your privilege.

23 MR. TISI: It involves the discussion <sup>24</sup> between counsel and in the drafting of the reports, what would be in, what would be out,

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<sup>1</sup> literature.

9

17

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24

25

Are all those notes something that became --<sup>3</sup> on a single document that ultimately became a 4 report?

A. It was one document that went through 6 numerous, numerous editing on my part and, of <sup>7</sup> course, suggestions from attorneys at different 8 points.

Q. Now, as an anatomic pathologist and as <sup>10</sup> the only pathologist that has been designated by 11 the plaintiffs in this MDL, did you think that it was important to opine on the pathogenesis of <sup>13</sup> ovarian cancer from an anatomic pathology standpoint?

15 MR. ROTMAN: Objection. For what 16 purpose?

MS. AHERN: I'm asking her.

Q. Can you answer the question?

19 A. First of all, I wasn't aware I was the only pathologist because I didn't have a list of 21 their named experts.

22 I did work on -- I'm not sure how much I can really talk about the whole draft process.

MR. ROTMAN: You can't --

Q. So my question was: As an anatomic --

<sup>1</sup> what she thought, what she didn't think. You're <sup>2</sup> not entitled to any of that.

MR. ROTMAN: So if you can find the question, read the question, and I will object to

the question, but you can answer it.

A. Okay. So you want me to reread the question?

MR. ROTMAN: To yourself.

9 So my question was -- do you see that? 10 THE WITNESS: Yeah.

A. Well, I feel as if I did that in my <sup>12</sup> final report. I certainly -- the -- my opinions 13 that are in my final report are certainly within the realm of gynecologic pathology.

Q. And can you specifically point to the opinions and the discussions in your report that are within your personal expertise in gynecologic pathology?

19 A. So, again, review of epidemiology is something that physicians do on a regular basis.

<sup>21</sup> We're trained to look at epi data. We're trained to practice evidence-based medicine, which has a

very similar, if not identical, methodology.

So -- and we certainly are trained in <sup>25</sup> inflammation, the immune system, talc and

- <sup>1</sup> tissue -- I have a section on talc and tissue --<sup>2</sup> the epi data.
- Not -- I don't think any of this report is 4 outside of my -- I know that none of this is
- <sup>5</sup> outside of my expertise as a gynecologic pathologist.
- Q. Okay. Doctor, were you retained as an expert epidemiologist in this case?
- A. I was retained as a gynecologic 10 pathologist.
- 11 Q. And you are not an epidemiologist; 12 correct?
- 13 A. I'm not a epidemiologist, but we <sup>14</sup> certainly review epidemiology and critique <sup>15</sup> epidemiology studies on a regular basis in our <sup>16</sup> daily practice.
- Q. When people ask you what you do for a 18 living, you don't tell them you're an 19 epidemiologist, do you?
- 20 A. I often have to explain what a 21 pathologist is, so I spend half the time just
- trying to describe what a pathologist is, so... 23 MR. KLATT: Objection. Nonresponsive.
- 24 MS. AHERN: Yeah.
- 25 MR. ROTMAN: She's not done answering

11

13

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- <sup>1</sup> your question. She's in the middle of an answer.
  - A. So my point is I'm unlikely to describe
- <sup>3</sup> myself as an epidemiologist when I'm trying to 4 describe what a pathologist does, but that's the
- <sup>5</sup> big picture.
- But the real picture is, on a daily basis,
- 7 we are evaluating epidemiologic data in the
- 8 literature.

13

- 9 BY MS. AHERN:
- 10 Q. When was the last time you did a 11 systematic review of the literature for the purpose of opining on causation?
  - A. So we review literature --
  - Q. You. I'm just talking about you.
- 15 A. Hold on one second. Let me just review
- the question. I'm way behind here on my --
- 17 Well, I do literature searches all the time
- 18 and looking -- when I'm looking at cases to 19 figure out causation.
- 20 I've been involved in one other legal case,
- 21 but it is -- this was the first medical-legal
- general causation report.
- 23 But, again, this is all the same methodology
- <sup>24</sup> that we use in evidence-based medicine and our practice.

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- Q. You do a full systematic review of the <sup>2</sup> literature, as that term is defined
- epidemiologically?
- A. We certainly do when we're doing
- research, when we're writing papers, but we still
- <sup>6</sup> do literature searches when we're assigning out
- cases that are relevant to individual patients.
- Q. When was the last time you conducted a
- full systematic review of the literature and a
- Bradford Hill analysis to opine on causation?
- A. So, again, this is not something that's completely foreign to me. The legal aspect of it
- is new to me, but this methodology is not new to 14 me.
- 15 The last time -- I mean, there was a tobacco
- case that I worked on, but in my daily practice,
- again, I'm still looking at epidemiology
- literature all the time.
- 19 Q. Well, there is a difference, Doctor,
- wouldn't you agree, between looking at the
- epidemiology to inform yourself about a
- particular issue and doing a systematic review of
- the literature and a full Bradford Hill analysis
- <sup>24</sup> to opine on causation? Is there a difference?
  - A. Well, this was a deep dive, so I'll say

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- <sup>1</sup> I was aware of the literature on talcum powder
- <sup>2</sup> and ovarian cancer before I became involved in
- <sup>3</sup> this litigation.
- I will say, you know, it wasn't until they
- asked me to form my opinion on this that I did a
- deep dive on the literature again on this
- particular issue.
- Again, I've certainly done extensive
- <sup>9</sup> literature reviews before to, you know -- in
- research and in practice.
  - Q. But nothing like this?
- 12 A. It's very similar.
  - MR. ROTMAN: Objection.
  - A. The methodology is very similar to
- 15 this. It's identical.
- 16 Q. Doctor, can you point me to -- take a 17 look at Exhibit 2, your CV.
- Can you point me to something in your CV
- that demonstrates some specialized knowledge or
- expertise in epidemiology? A course, a class
- you've taught? A paper that you've published? A
- 22 case-control study you've been involved in?
- Anything that would indicate that you have
- specialized expertise in epidemiology? 25
  - A. It's part of our medical training as

1

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- 1 part of evidence-based medicine.
- I'm trying to find my CV. I'm not sure I
- <sup>3</sup> have it in front of me. Maybe it's under here.
- 4 Well, you're sitting in -- I mean, all of these
- <sup>5</sup> involved epidemiology research.
  - MR. ROTMAN: All of what?
- A. I'm sorry. All of these research
- projects start with -- the pathology publications
- <sup>9</sup> start with looking at the literature of
- <sup>10</sup> epidemiology.

6

- 11 Q. Which ones are you pointing to --
- 12 sorry. Let's look at the peer-reviewed
- <sup>13</sup> publications.
- 14 Is that what you're talking about?
- 15 A. Yes. Sorry.
- 16 Q. So the first publication is Narasimhan,
- 17 "Temperature Induced Interstrand Crosslinks in
- 18 Cisplatin-DNA Adducts Detected by Electrophoresis
- and UV Spectrophotometer."
- 20 That's not an epi study, is it?
- 21 A. Some of these were biology. The one
- 22 that comes to mind when I'm looking at this list
- 23 is the "Yersinia pestis and the plague." That
- 24 was a review article. That was around -- that
- <sup>25</sup> was after the 2001 mailings of the pattern
- Page 219
- <sup>1</sup> substance. And so the literature was very
- <sup>2</sup> interested in Yersinia pestis at the time, and so
- <sup>3</sup> I did a review article on that.
- Q. Was that a systematic review and a
- <sup>5</sup> Bradford Hill analysis?
- A. The Bradford Hill analysis is part of
- evidence-based medicine when you're coming to a
- conclusion. So --
- 9 Q. This isn't a case-control study or a
- prospective cohort study --10
- 11 MR. ROTMAN: You're not allowing her to
- 12 finish her answer.
- Q. -- or epidemiology study, is it?
- A. But my general causation opinion is
- <sup>15</sup> very similar to a review article on causation.
- <sup>16</sup> It's a review of the epi data and mechanisms.
- 17 Q. Did you do a full review of the epi
- <sup>18</sup> data and mechanisms on Yersinian plague?
- 19 It's kind of a done deal; right? We already
- 20 know that; isn't that right?
- A. Well, you're still looking at -- you're
- 22 still looking at data. The question is -- the
- <sup>23</sup> question was at the time: Can Yersinia pestis be
- <sup>24</sup> a dangerous weapon of destruction or
- <sup>25</sup> terrorist-type agent?

- Page 220 So that was sort of more the review on that.
- Q. Who is S.M. Rollins?
- 3 A. That's my ex-husband.
  - Q. What is his specialty?
- 5 A. He's a microbiologist. 6
  - Q. What about Ryan?
    - A. He is an infectious disease physician.
- Q. Okay. What portion of "Yersinia pestis
- and the plague" did you draft or did you
- contribute?
- 11 A. I drafted the entire -- I was the lead
- author, and I -- the primary author, and I
- drafted that report.
  - Q. Okay. So if we go in there, we're
- going to find you used statistical methods or
- analysis in any way to weigh the evidence and
- conduct a systematic review?
  - A. It's definitely a review article. Off
- the top of my head, I don't know if I did a
- 20 statistical analysis, but...
- 21 Q. Would you describe it as more of a
- narrative review of the literature?
- 23 A. A review of the literature. I don't
  - know about the word "narrative," but review.
    - Q. What about the Grundy paper,

Page 221

- <sup>1</sup> "Specificity of tRNA-mRNA Interactions in
- <sup>2</sup> Bacillus substilis tyrS Antitermination"?
- Is that an epi study?
- 4 A. No.
- Q. What about the Rollins paper,
- "Diagnostic yield of muscle biopsy in patients
- with clinical evidence of mitochondrial
- cytopathy"?
- 9 Is that an epidemiologic article?
- 10 A. No. That's not an epidemiology
- 11 article, but we --
- 12 Q. Sorry?

- A. It's getting late in the day.
- 14 MR. TISI: Do you need some water?
- 15 THE WITNESS: Sure.
- 16 A. But it's interesting that it actually
- did involve electron microscopy. And when we do
- muscle biopsies for mitochondrial cytopathy, we
- use electron microscopy anyway, regularly.
- 20 MR. KLATT: Objection. Nonresponsive.
- 21 Q. And what about the Rollins
  - "Autoimplants and serous borderline tumors of the
- ovary: A clinicopathologic study of 30 cases and
- a process to be distinguished from serous
- adenocarcinoma"?

- Was that a systematic review of the
- <sup>2</sup> literature, or an epidemiologic study?
- A. There's definitely review of literature
- 4 as part of that study because the question arises
- <sup>5</sup> with autoimplants, sometimes they're misdiagnosed
- 6 as invasive serous.
- So there is definitely literature review forthat study.
- <sup>9</sup> Q. This would be described as you have it
- <sup>10</sup> in the title, this is a clinicopathologic study?
- 11 A. Correct.
- Q. So you were looking at this as a
- <sup>13</sup> pathologist; correct?
- A. Well, I'm looking at -- I mean, some of
- 15 these were before I was -- the first couple are
- <sup>16</sup> before I was an M.D., but all of the subsequent
- ones I'm looking at as a pathologist.
- Q. What about the Chan study,
- 19 "Clinicopathologic Correlation of Fetal Vessel
- <sup>20</sup> Thrombosis in Mono- and Dichorionic Twin
- 21 Placentas"?
- Is that an epidemiologic study?
- A. That's a clinicopathologic correlation.
- Q. And then the publication with Jonathan
- <sup>25</sup> Hecht, "Endometrial Interepithelial Neoplasia,"

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- <sup>1</sup> is that an epidemiology study?
- A. That was a review of a new terminology
- <sup>3</sup> in endometrial precursor lesions. So that was a
- <sup>4</sup> pathologic -- an anatomic pathology article.
- <sup>5</sup> Q. And then you have the one with Haspel,
- <sup>6</sup> which is "Successful Implementation of a
- <sup>7</sup> Longitudinal, Integrated Pathology Curriculum
- <sup>8</sup> During the Third Year of Medical School"?
- <sup>9</sup> A. That was a medical-education-type <sup>10</sup> article.
- Q. Okay. And do you have any proceedings
- <sup>12</sup> of meetings, poster presentations, that were from
- <sup>13</sup> a case-control or a cohort study that you
- 14 conducted?
- A. Let me look. I don't believe these
- <sup>16</sup> poster presentations were case -- well, I mean,
- <sup>17</sup> case-control or cohort epi-type studies.
- Q. Okay. And, Doctor, to be fair, you
- <sup>19</sup> don't have a degree in epidemiology; correct?
- A. I do not have a degree. But, again,
- 21 it's -- epidemiology is a very big part of
- <sup>22</sup> evidence-based medicine and what we practice as
- 23 M.D.s.

25

- MR. KLATT: Objection. Nonresponsive.
  - Q. And, Doctor, you understand that there

- <sup>1</sup> are degreed epidemiologists who have been
- <sup>2</sup> designated on behalf of plaintiffs to look at
- <sup>3</sup> these issues; correct?
- A. I'm aware of that now. I didn't know
- who their list was before I submitted my report.
- Q. You've never published -- as we just
- <sup>7</sup> looked through here -- an epidemiologic study, a
- 8 case-control study, or a cohort study?
  - A. I have not published; but, again, that
- 10 doesn't -- I mean, it doesn't mean I haven't done
- 11 them. It's just that --
  - Q. Have you done them?
  - A. They haven't been published. Well,
- <sup>14</sup> again, literature reviews of epidemiology is part
  - <sup>5</sup> of our regular practice.
- Q. I'm asking about, like, actual study
- <sup>17</sup> designs.

12

13

21

- Have you conducted a case-control or a
- 19 cohort study?
- A. Not of an epi- --
  - Q. Okay.
- <sup>22</sup> A. -- specific design.
- Q. Have you ever taught an epidemiology
- 24 course?
  - A. No.

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- Q. Do you have any grant funding to
- <sup>2</sup> conduct epidemiologic observational studies?
  - A. No.
- <sup>4</sup> Q. Have you ever given any lectures or
- <sup>5</sup> presentations specifically on epidemiology
- 6 methodologies?
  - A. That's possible. I'm trying to think.
- <sup>8</sup> It's been a long time. Medical school through
- <sup>9</sup> residency, fellowship, not that I can think of
- off the top of my head.
- Q. Okay. And have you ever designed a clinical trial?
  - A. I have not designed a clinical trial.
  - Q. Have you designed a case-control study?
- <sup>15</sup> A. I have not designed a case-control
- 16 study.

13

14

- Q. Have you designed a cohort study?
- A. I have not designed a cohort study;
- <sup>19</sup> but, again, these are -- we can critically
- <sup>20</sup> evaluate. Just because I haven't designed one
- <sup>21</sup> doesn't mean I can't critically evaluate
- <sup>22</sup> case-control studies or cohort studies.
- Q. Doctor, you haven't conducted a
   meta-analysis or a pooled analysis to evaluate
- potential risk factors for any disease, have you?

A. No, I haven't.

1

Q. Are you qualified to conduct a

<sup>3</sup> meta-analysis or a pooled analysis?

- A. I'm -- I'm sure I could develop one.
- Q. As we sit here today, are you qualified
- <sup>6</sup> to conduct a meta-analysis or a pooled analysis?
  - A. If it was sort of a joint venture, I'm
- 8 sure; but, again, that doesn't mean that I can't
- <sup>9</sup> critically evaluate them, because that's what I
- odo on a daily basis.
- Q. Have you authored any paper or
- 12 conducted a study -- well, have you authored any
- paper on the methods of causal interpretation?
- A. Have I authored a paper on the methods
- <sup>15</sup> of causal interpretation?
- <sup>16</sup> I don't believe I've authored. It would be
- <sup>17</sup> on my list.
- Q. Okay. Doctor, I should have asked you
- 19 this when it was in front of you: Do you have a
- <sup>20</sup> copy of that one-page additional materials?
- A. Probably. Let's see.
- Q. Thank you. Maybe I have. Maybe I have
- <sup>23</sup> it too.
- <sup>24</sup> A. Exhibit 17?
- O. Yes. Yes.

- <sup>1</sup> asbestos in it, that would certainly add to the
  - <sup>2</sup> plausibility of causation.
  - O. If there was not asbestos in talcum
  - 4 powder products and there was not fragrance in

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- <sup>5</sup> talcum powder products and you were just left
- <sup>6</sup> with the pharmaceutical-grade talc, what would
- <sup>7</sup> your biologic plausibility argument be?
  - MR. ROTMAN: Objection.
  - Q. In other words, what is your mechanism
- by which pharmaceutical-grade talc would cause
- 11 ovarian cancer?
- MR. ROTMAN: Objection. Are you asking
- <sup>3</sup> about causation or about biological plausibility?
- MS. AHERN: I'm asking --
  - MR. ROTMAN: You mixed them.
- MS. AHERN: -- about her mechanism.
- <sup>17</sup> BY MS. AHERN:
- Q. What is your mechanism by which
- <sup>19</sup> pharmaceutical-grade talc would cause ovarian
- 20 cancer?

15

- A. So there are -- again, most of the
- studies are dealing with talc powder products.
- <sup>23</sup> If we were to say that all that was in there is
- <sup>24</sup> pharmaceutical -- it's completely hypothetical
- <sup>25</sup> because I don't know what's in there -- I still
- Page 227
- You received a copy of the Longo
- <sup>2</sup> supplemental report; correct?
- <sup>3</sup> A. I did. Yes.
- 4 Q. And it's, what, 404 pages?
- 5 A. That's possible. I don't think I
- 6 looked.
- <sup>7</sup> Q. That was my next question: Did you
- 8 review it?
- 9 A. I did review it. I did skim a lot of
- 10 it because, again, it was additional information
- 11 that was nice to have, but it was after my
- <sup>12</sup> report.
- And, again, my general causation opinion is
- 14 not dependent on asbestos being in the product.
- 15 My general causation opinion is based on whatever
- 16 is in the bottle. So it was interesting
- <sup>17</sup> information to have.
- Q. So your opinions here, it doesn't
- 19 matter for your opinions whether or not there's
- <sup>20</sup> asbestos in talcum powder products; is that your
- 21 testimony?
- A. What I'm saying is my opinion is based
- 23 on whatever is in the talcum powder product's
- 24 bottle. Now, it's up to the jury to decide if
- 25 there's asbestos in it. However, if there is

- <sup>1</sup> think the mechanisms would be similar where, you
- <sup>2</sup> know, there's evidence that talc can cause
- <sup>3</sup> inflammation, and we know that inflammation is a
- <sup>4</sup> cause of cancer.
- 5 And so I -- and there's also, you know,
- <sup>6</sup> Dr. Cramer talked about anti-MUC-1 antibodies, so
- 7 there's an immune -- plausible immune mechanism,
- 8 so I think all of those are still on the table
- <sup>9</sup> and the hypothetical situation that it's only
- 10 pharmaceutical-grade talc in that bottle.
- But, again, I -- I'm not opining about what
- 12 is in the bottle; I'm just opining about that --
- whatever that product is in that bottle causing
- <sup>4</sup> ovarian cancer.
- Q. Okay. Let's take a look at your expert report again, Exhibit 14, if you will.
- Just let me know when you've got it.
- 18 A. Yeah

- Q. Okay. Doctor, does Exhibit 14, your
- 20 November 15, 2018, expert report, contain all of
- 21 the opinions that you intend to offer as a
- witness in this matter?
- A. I wouldn't box myself in that way.
- 24 There might be questions that I'm asked here
- today or in trial that aren't necessarily in my

<sup>1</sup> report.

Q. Okay. But the opinions that you intend <sup>3</sup> to offer, absent somebody asking you to offer

4 other opinions, are all outlined or contained

<sup>5</sup> within Exhibit 14, your report; is that correct?

A. Again, I wouldn't want to say "all." I

<sup>7</sup> wouldn't want to limit myself. There's always

8 the possibility that something else will come up,

<sup>9</sup> and I even have a thing that additional

<sup>10</sup> information may come up.

11 Q. Okay. As we sit here today, do you 12 understand that this is our opportunity to ask

you about the opinions in your report, and we

14 have the day to do it?

15 Do you understand that?

16 A. I understand.

17 Q. Okay. So to the extent that you think

you're going to offer additional opinions or

different opinions, we need to know that today.

I understand that if something comes up two

weeks from now and it's additional information,

you might supplement your report.

23 But as of today, as we sit here today, is

24 this report an accurate reflection of the

opinions that you have formed and that you intend

<sup>1</sup> probably have within them all the references to

<sup>2</sup> your report. Other than those and what you

<sup>3</sup> brought with you today, is there anything else

4 related to your work on your report that you have

<sup>5</sup> in your possession that you haven't been able to

6 bring with you today?

A. Not that I'm aware of. I've tried to

8 be very complete in my list of what I reviewed.

It's possible -- again, it's possible there are a

couple of things that might have been left off,

but I tried to be as complete as possible.

Q. Okay. And you mentioned earlier you

had done some work on the pathogenesis of ovarian

14

15

21

Did you have any articles or publications

16 that are related to that work that are not

referenced in your report?

A. I believe they should be in the list.

They should be included in the list that you

20 have.

Q. The one from -- your initial report?

22 A. Taken all together. Taken all

together. So that, probably, is more -- the

January 4th one would probably be some of those.

And then I can't remember what's on that one

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1 to offer in this case?

A. I would say it's an accurate reflection

<sup>3</sup> of the opinions I have formed with the exception

4 of anything that might be asked that is not in

<sup>5</sup> the report; but yes.

6 Q. All right. All right.

7 And as we sit here today, is your report

complete? 8

10

25

9 A. Well, it's signed and turned in, so --

Q. Do you, as the expert designated in

11 this case, Sarah Kane, do you consider your

report to be complete as we sit here today?

13 A. Yes.

14 MR. ROTMAN: Off the record.

15 (Discussion off the record.)

16 THE VIDEOGRAPHER: Off the record,

17 3:24 p.m.

18 (A recess was taken.)

19 THE VIDEOGRAPHER: Here begins Media

No. 5 in today's deposition of Sarah Kane, M.D.

21 Back on the record, 3:39 p.m.

22 BY MS. AHERN:

23 Q. Okay. Dr. Kane, we were talking about

24 your report. Just some basic housekeeping first.

We have the four boxes back here which

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<sup>1</sup> that you just got, but if there's a couple on

<sup>2</sup> there.

But I would think if they weren't cited in

4 the report, the majority of those should be in

the January 4th list.

Q. Okay. And those would pertain to the

various histologic categorizations of ovarian

cancer; what is known about etiology.

9 Is that kind of the gist of the information

10 that you researched? 11

A. Yes. Yes. That was certainly part of

<sup>12</sup> it.

13

14

22

Q. And were there other parts to that?

THE WITNESS: Is that -- I don't know

<sup>15</sup> if --

16 MR. ROTMAN: Yeah. You can say what 17

work you did.

A. There was -- so a good bit of it was

sort of background information on the pathologic

diagnosis of ovarian cancer and different, as you

said, different subtypes.

There was -- I'm trying to remember -- it

was so long ago -- what some of the -- I believe

there was a little bit more on inflammation, but

<sup>25</sup> I can't say for sure.

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<sup>1</sup> BY MS. AHERN:

- Q. And would that have been just related
- <sup>3</sup> to ovarian cancer pathogenesis?
- A. Yes. Yes.
- Q. And you think that all of the
- <sup>6</sup> publications that you found, identified, reviewed
- <sup>7</sup> in relation to that work are identified in one of
- 8 the lists or across several lists?
- 9 A. I'm hoping that across all of the
- 10 lists, that encompasses the vast majority, if not
- 11 all. But let's just keep it at vast majority.
- 12 And, of course, you know, I'm a gynecologic
- pathologist, so I read tons of other stuff that,
- 14 you know, is just my background knowledge that
- <sup>15</sup> I'm not going to put on these lists. So I can't
- <sup>16</sup> say it's all-inclusive; but, again, I tried.
- Q. Understood. Understood.
- 18 And you've now seen at least one report from
- <sup>19</sup> Dr. Robert Kurman; correct?
- 20 A. That's correct. That was an individual
- 21 causation report, though. So...
- 22 Q. And he had a very large background
- 23 section on ovarian cancer pathogenesis; correct?
  - A. To be honest with you, I sort of
- skimmed it, but I do remember seeing a section on

- Page 236
- <sup>2</sup> the product of your own work?
- A. Yes. I wrote the report. Certainly,
- <sup>4</sup> again, there were drafts that went back and
- forth. There may have been suggestions from

<sup>1</sup> Exhibit 14, your expert report, are they solely

- attorneys where language was -- that I accepted
- into my report; but yes.
- Q. Okay. You didn't borrow language from
- other experts or from other publications and then
- not quote that in your report?
- 11 A. I certainly tried not to. No. I
- 12 certainly cited anything that I -- I tried to
- cite everything that I referenced --
- 14 Q. Okay.

15

- A. -- to the best of my ability.
- 16 You know, again, I was taking the notes as I
- wrote, so it's plausible there might be
- something, but I was very cognizant of trying not
- to -- trying to cite everything that I was
- referencing.
- 21 Q. And in reaching your opinions, was it
- 22 important to you that you review the data in a
- fair and objective way?
  - A. Yes. I think it's always important to
- <sup>25</sup> review data in a fair and objective way.

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- <sup>1</sup> that. Yes.
- Q. Okay. Did you skim the section that <sup>3</sup> was case-specific?
- A. No. Mostly the background since I
- already know that stuff.
- Q. Okay. And is the stuff that was in his <sup>7</sup> background section similar to the research that 8
- you did?
- 9 A. I would say yes. If I am remembering
- accurately, it was similar. I wouldn't say
- <sup>11</sup> identical, but similar.
- 12 Q. Okay. And did anyone other than your attorneys assist you in preparing the report?
- 14 A. No.

19

22

- 15 Q. And you said earlier, I think, that you
- didn't consult with any of the other experts in
- the MDL litigation in forming your opinions or
- 18 preparing your report?
  - A. That's correct.
- Q. And you didn't review any draft reports
- <sup>21</sup> from any other experts in this litigation? A. No. The only time I saw their reports
- was after we had all turned them in to the court.
- Q. Okay. And are all of the words, the
- <sup>25</sup> ideas, the analysis that's contained in

Q. I know. It's kind of a basic question.

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- When you were doing your literature reviews
- <sup>3</sup> and searches, were you looking both for papers or
- <sup>4</sup> data that supported talc and ovarian cancer
- connection as well as for data and literature
- 6 that did not or that -- well, that did not
- support?
- A. When I was doing my literature search,
- <sup>9</sup> I was looking for any data that spoke to talcum
- powder products and ovarian cancer. I was really
- 11 trying to cast as wide a net as possible to get
- <sup>12</sup> as much data as I could.
  - Now, certainly, there are limitations when
- you're doing searches. It's possible there are
- studies that I missed; but when I was retrieving
- studies, reading them, I would also reference
- their references as a sort of cross-check. So I
- tried to be as complete as I could.
- 19 Q. So when you were reading someone else's work and they referenced an article as the basis
- for synthesis or the statement in their paper,
- <sup>22</sup> did you then go and review the underlying
- 23 reference as well?

- 24 A. Yes. I pulled up those references.
  - Q. Okay. And you reviewed those as well?

A. Yes.

1

- <sup>2</sup> Q. Okay. And you mentioned on Page 4 of <sup>3</sup> your report that your interest in talc and
- <sup>4</sup> ovarian cancer began during your training, your
- fellowship training, at Mass General; is thatright?
- A. I became aware of it. I mean, both
- <sup>8</sup> Dr. Scully and Dr. Bell were still there at my
- <sup>9</sup> time of training, and Dr. Scully was a coauthor on Cramer's first 1982 paper.
- And then Dr. Bell was a coauthor in one of the subsequent -- I think his 1992 paper with Harlow.
- So I was certainly aware of literature on
   talcum powder and ovarian cancer.
- Q. And neither one of them published anything else on talc; is that correct?
- <sup>18</sup> A. I believe those were the only two that <sup>19</sup> they were on. That's correct.
- Q. And did you understand that the role that Dr. Scully played on Dr. Cramer's first publication was simply that of pathologist and determining or confirming the diagnosis of the samples that were being studied?
- A. I was aware that he did a pathologic

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- $^{\, 1}$  I know we talked about the Nurses' Health Study.
- That's funny, though, I actually did talk --
- <sup>3</sup> I saw Jonathan last night, so it's kind of funny
- <sup>4</sup> timing. But anyway...
- Q. Have you talked to Dr. Hecht since
- 6 then, since you first discussed with him the
- <sup>7</sup> Nurses' Health Study?
- <sup>8</sup> Have you spoken with him on talc and ovarian
- <sup>9</sup> cancer?
- A. Yes. I saw him last night. We went out for a drink.
- Q. Did he give you any opinions on what he thought about talc and ovarian cancer?
- A. He told me that he had met with defense counsel at one point; did not want to do medical expert witness work but did a brief sort of intro, I guess, overview for the defense.
- Q. Did he tell you what his personal or his professional opinion was on whether or not talc causes ovarian cancer?
- A. Yes. He thought that -- so I'll say in my report, I did not spend a lot of time on
- <sup>23</sup> migration because in the gynecologic world, it's
- <sup>24</sup> widely accepted that migration happens. He told
- $^{25}\,$  me that he specifically told the defense counsel

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<sup>1</sup> review of the case.

- Q. Okay. Did you ever have an opportunity to talk to Dr. Scully about talc and ovarian cancer?
- A. I believe my conversations were -- my memory is -- this is 20 years ago now -- it's
- possible, but probably with Dr. Bell, more. I
  interacted more with Dr. Bell than Dr. Scully.
- <sup>9</sup> Dr. Scully was semiretired at the time. He
- $^{10}$  would come in for half the day, but that was
- 11 usually when I was with other attendings. But I
- did spend a significant time with Dr. Bell, and I
- do remember being aware of that literature.
   Now, if you're going to ask me the specific
- conversation, I probably can't prompt that at the moment.
- I was also, when I was at Beth Israel
- 18 Deaconess, my colleague Jonathan Hecht is there.
- <sup>19</sup> And I was aware he was doing work on the Nurses'
- <sup>20</sup> Health Study.
- We didn't -- I can't remember if we really
- 22 talked about talc at that point because the Gates
- 23 2010 paper that he was doing, talc was a very
- 24 small -- it was almost, like, a side comment in
- 25 that report. But I think we had talked about --

- <sup>1</sup> he met with not to use migration because it's
- <sup>2</sup> widely accepted that it occurs.
- We did talk about the Nurses' Health paper.
- <sup>4</sup> He said that the data set was very small, it was
- <sup>5</sup> very difficult with classification, and that
- 6 that -- there just really wasn't a lot of data in
- 7 that 2010 study.

- 8 And he thinks that it is plausible for
- <sup>9</sup> talcum powder to cause ovarian cancer.
  - Q. Have you spoken to any other
- pathologist or colleagues about talc and ovarian cancer?
- A. I have talked to my coworkers about it
- because -- as a conflict-of-interest notification
- <sup>15</sup> for our group and for our hospital, Partners
- Healthcare, and I discussed my findings with mypartners.
- And I've also talked about it at
- <sup>19</sup> multidisciplinary conferences; recently at, for
- example, at a thoracic conference. There were
- gyn oncs there and radiologists and rad oncpeople there.
- Q. And you talked to them specifically about talc and ovarian cancer?
  - A. So I told them about my work on it and

- <sup>1</sup> the research that I had done, and I was asking
- <sup>2</sup> them -- it was a thoracic conference, so I was
- <sup>3</sup> curious if any of them had asked any of their
- 4 mesothelioma patients that didn't have
- <sup>5</sup> nonasbestos exposure if they've ever asked them
- <sup>6</sup> if they'd had talc exposure.
- And they said no, they hadn't really done
- 8 it, they hadn't thought about it, but maybe it
- <sup>9</sup> was something that they should be asking.
- Q. And, by the way, what were the
- $^{\rm 11}\,$  circumstances under which you and Dr. Hecht had
- 12 dinner the other night?
- A. His birthday is coming up. We're still
- 14 friends, so it was one of these -- I actually
- 15 stayed in a hotel last night because it took me
- <sup>16</sup> an hour and a half to drive from Topsfield
- <sup>17</sup> yesterday morning, and I didn't want to be
- 18 worried about traffic. So I decided to stay in a
- 19 hotel last night. His birthday is coming up, so
- <sup>20</sup> I said, "Let's just grab a drink."
- Q. You mentioned while you were at Mass
- <sup>22</sup> General, the fellowship director for your program
- was Robert Young; correct?
- <sup>24</sup> A. Yes.
- Q. Is he someone that you look up to as a

- <sup>1</sup> Dr. Scully retired; is that right?
- A. Yes. He inherited his consult service.

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- <sup>3</sup> So it's a separate service from our regular
- <sup>4</sup> clinical work. So it's pathologists from all
- <sup>5</sup> over the country or even world that have
- <sup>6</sup> difficult cases, they will send as a specific
- <sup>7</sup> private consult to -- it was Dr. Scully, and now
- 8 it's Dr. Young.
- <sup>9</sup> Q. Okay. When you were first contacted by
- the plaintiffs' counsel back in 2017, what were
- your opinions regarding talc and ovarian cancer
- <sup>2</sup> at that point?
- <sup>13</sup> A. First contacted? When I was first
- <sup>14</sup> contacted, I was aware of the literature,
- <sup>15</sup> certainly. I hadn't come to a strong opinion one
- <sup>16</sup> way or the other. In fact, I'd probably say I
- was aware that the epi data had been relatively
- 18 consistent. That was kind of all I knew about it
- <sup>19</sup> until I did my sort of deep dive into the
- literature for my general causation opinion.
   O So as a pathologist, you never had a
- Q. So as a pathologist, you never had a
- <sup>22</sup> particular interest in pursuing additional
- 23 research in the area --
  - MR. ROTMAN: Objection.
  - Q. -- of talc and ovarian cancer?

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- <sup>1</sup> pathologist?
  - A. Yes. He's very well-respected.
- <sup>3</sup> Q. By the way, who do you send second
- <sup>4</sup> opinion consults to when you have a difficult
- 5 case?
- <sup>6</sup> A. We have a relationship with Mass
- <sup>7</sup> General, so I'll occasionally send -- if I need
- 8 another set of eyes on, I'll send it to either --
- <sup>9</sup> it's sort of their gyn pathology group in
- 10 general, so it might be Dr. Young. It might be
- 11 Esther Oliva. Those are the two that I would say
- 12 most frequently would receive any consults from
- our group for gyn path.
- 4 Q. Have you ever spoken with Dr. Young
- <sup>15</sup> about talc and ovarian cancer?
- <sup>6</sup> A. It's possible. I haven't recently. He
- and I aren't in regular communication, so I
- 18 certainly wouldn't have talked to him -- I don't
- 19 know if I've talked to him since starting this.
- It's more of a professional-type
- <sup>21</sup> relationship, so I don't know if it would have
- 22 come up recently. But it's possible in training,
- <sup>23</sup> but I don't remember specifically.
- Q. And Robin Young inherited all of
- <sup>25</sup> Dr. Scully's case files in his office when

- A. Well, there's certainly a lot of things
- <sup>2</sup> to study in gynecologic pathology. And so I
- <sup>3</sup> hadn't decided to take that -- to do that study
- <sup>4</sup> at the time that I was contacted by counsel.
- <sup>5</sup> That's not to say I never would have or I never
- 6 would have thought about it, but I hadn't at the
- 7 time.
- Q. Okay. In your report on Page 4, you
- 9 say that you've maintained a professional
- o interest -- "since your fellowship, you've
- maintained a professional interest and have
- <sup>12</sup> continued to monitor developments in the science
- 13 regarding talcum powder exposure and ovarian
- cancer, and it has been the subject of
- <sup>15</sup> professional discussions predating the
- <sup>16</sup> litigation."
- So what sort of professional discussions
- 18 about talc and ovarian cancer did you have before
- the plaintiffs retained you?
- A. So, again, I was aware of the
- 21 literature. And I knew -- I saw some of the
- newer epi data come out. I had had conversations
- <sup>23</sup> with Dr. Bell that I remember specifically;
- again, with Jonathan. I knew he was working on
- 25 that Nurses' Health. We certainly talked about

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- <sup>1</sup> that study at some point.
- But, you know, I was certainly aware of the
- <sup>3</sup> literature as it came out.
- 4 Q. And you call it a "professional
- 5 interest."
- 6 Did you take -- other than just reviewing
- <sup>7</sup> the literature, did you do anything
- 8 professionally to either advance your knowledge
- <sup>9</sup> or other people's knowledge about this potential
- 10 association?
- 11 A. Not -- I mean, not at the time. I
- 12 think "professional interest" in my mind, you
- 13 know, means being aware of what's going on in the
- 14 literature. Again, that doesn't necessarily mean
- <sup>15</sup> an in-depth review of everything but being
- <sup>16</sup> generally aware of it.
- Q. Would you say that since you first
- 18 learned about this in your fellowship and were
- 19 interested in the topic, did it influence the way
- <sup>20</sup> you looked at gynecologic cases as a professional
- <sup>21</sup> pathologist?
- A. Yeah. It's not really routine practice
- 23 to use polarized light microscopy in gynecologic
- <sup>24</sup> pathology. It's just -- we use it more commonly
- <sup>25</sup> for breast cases, so...

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- And also, you know, even if we found
- <sup>2</sup> birefringent particles and granulomas or -- in
- <sup>3</sup> the tissue, it wouldn't necessarily mean that
- <sup>4</sup> they're talc unless you do subsequent studies.
- So I wouldn't say it changed my daily
- practice in diagnosing tumors.
- Q. Okay. Doctor, if you can turn to
- <sup>8</sup> Page 4 and 5 of your report.
- 9 Is this where you set out a summary of your 10 opinions?
- <sup>11</sup> A. Yes. This is.
- Q. Under Heading 2, Page 4, "General
- 13 causation opinions."
- <sup>14</sup> A. Okay.
- Q. And you list, it looks like, five specific opinions; is that correct?
- A. I see where you are. Yes.
- Q. And are those -- again, are those all the opinions that you have that you intend to
- <sup>20</sup> offer in this case?

- MR. ROTMAN: Objection.
- A. Same answer as before. Again, there
- <sup>23</sup> might be something that comes up today or at
- trial that I'm asked that I, you know, didn't put
   in this report. But I tried to be as -- complete

- <sup>1</sup> in the report.
- Q. Okay. And the first opinion is that
- <sup>3</sup> talc can migrate to the ovaries through the
- <sup>4</sup> genital tract through the lymphatic system and
- <sup>5</sup> through inhalation.
- Is that an accurate summary of your first
- opinion or set of opinions?
  - (reading from document)
- A. Yes. The talcum powder products can
- reach the ovaries; that they can be transported
- through the lymphatic system; and there is
- evidence that it can be inhaled as well with
  - transport to the ovaries.
  - Q. And the second opinion in the case or
- <sup>15</sup> second set of opinions is that talc causes
- <sup>16</sup> chronic inflammation in the ovaries, causes
- 17 increased oxidative stress in the ovaries, and
- 18 causes immunosuppression.
- 19 Is that an accurate summary of your
- 20 mechanism?
- A. Well, if you're going to read it word
- <sup>22</sup> for word, it's "Once reaching the ovaries, talcum
- 23 powder products can cause chronic inflammation,
- can increase oxidative stress, and can reduce
- <sup>25</sup> immune response. These are biologically
  - Page 249
- <sup>1</sup> plausible and likely mechanisms for ovarian
  - <sup>2</sup> cancer development and progression."
  - Q. Okay. When you say "reduce the immune
  - <sup>4</sup> response," is that essentially discussing, like,
  - <sup>5</sup> an immunosuppressive effect?
  - A. That's referencing the MUC-1 antibody
  - <sup>7</sup> paper that Cramer published in 2005.
  - Q. Are you aware that Dr. Cramer himself
  - <sup>9</sup> has disclaimed that theory as a "hypothesis
  - that's not ready for prime time"? I believe
  - <sup>1</sup> those were his words, "prime time."
  - A. I don't know where you saw those words.
    - Q. His testimony in the litigation.
  - A. Okay. I don't believe I saw his
  - testimony in the litigation. But, again, it's
  - not -- I'm not seeing it as something that needs
  - -- not -- I in not seeing it as sometiming that needs
  - <sup>7</sup> to be proven. I'm looking at it as a
  - <sup>18</sup> plausibility that, you know, it's a plausible
  - <sup>19</sup> mechanism. If it's not proven, it doesn't really
  - 20 change the fact that it's plausible.
  - Q. So are you building -- so is your plausibility opinion independent of whether or
  - 23 not the basis for that opinion is proven?
    - MR. ROTMAN: Objection.
    - Q. In other words, are you -- do you have

Filed 05/30/19 Page 314 of 565 PageID: ane, M.D. Page 250 Page 252 <sup>1</sup> a plausibility opinion that's based on a bunch of <sup>1</sup> reaching the ovaries. <sup>2</sup> other potential or plausible mechanisms? So -- and, again, it's widely accepted in 3 MR. ROTMAN: Objection. <sup>3</sup> the gynecologic community that migration occurs. 4 In fact, endometriosis, we really -- the evidence 4 A. Right. 5 MR. ROTMAN: I just objected, but you <sup>5</sup> is that endometriosis is caused by retrograde 6 can answer. If you can understand the question, 6 menstruation of endometrium. So there's a substantial amount of evidence you can answer it. A. Well, I think -- I think they're all and widely accepted that migration occurs. And I'm aware of studies that didn't find somewhat interrelated. I think there's the chronic inflammation. migration, but I think, you know, those few 11 There's the immune response. Those are plausible negative studies don't cancel out the positive studies. 12 mechanisms for ovarian cancer. 13 13 And the Bradford Hill guidelines, you don't And, you know, certainly, looking for migrated particles is very difficult. You know, 14 have to prove -- prove mechanism in order to have 15 causation. We have plenty of -- again, plenty of again, we're talking about dose. How much do you <sup>16</sup> examples of that in prior diseases, like smoking inject to get there? 17 <sup>17</sup> and lung cancer. And even certain drugs, they And so I think the positive studies are <sup>18</sup> don't know the mechanism of action, very common 18 compelling, and it's widely accepted that <sup>19</sup> drugs like lithium, for example, or metformin. migration occurs. 20 20 So you don't need to prove mechanism in (Article entitled "Presence of 21 order for it to be an important part of a 21 Talc in Pelvic Lymph Nodes of a Woman with 22 causation because it's part of the plausibility 22 Ovarian Cancer and Long-Term Genital 23 Exposure to Cosmetic Talc" marked Exhibit component. 24 Q. Do any of the bases on which you -- any 24 19.) of the bases that you use to support plausibility 25 Page 251 Page 253 <sup>1</sup> for talc and ovarian cancer, do any of them have <sup>1</sup> BY MS. AHERN: <sup>2</sup> to be proven or established? Q. Doctor, I'm handing you what's been MR. ROTMAN: Objection. marked as Exhibit 19 to your deposition. A. I think it's important to have evidence A. Okay. <sup>5</sup> to support it. There may be evidence that 5 MR. TISI: Thank you. 6 refutes it as well, but you're sort of looking MS. AHERN: You're welcome. <sup>7</sup> at -- you're balancing the weight of it. Q. Exhibit 19 is an article drafted by And the plausibility, a plausible mechanism, Dr. Dan Cramer, the "Presence of talc in pelvic 9 now, is that always going to be probable or lymph nodes of a woman with ovarian cancer and 10 definite? No. It's plausible. long-term genital exposure to cosmetic talc." 11 11 In this case, I think it's a compelling Is this a paper that you were referring to a

- 12 mechanism, chronic inflammation, because, again,
- 13 we know that talcum powder can reach the ovaries,
- 14 and we know that it can cause chronic
- 15 inflammation, and we know chronic inflammation is
- <sup>16</sup> implicated in cancer.
- 17 So I think it's a high degree of
- <sup>18</sup> plausibility in that case.
- 19 Q. So when you mention that you know that
- 20 talc can reach the ovaries, are you referring to,
- 21 for example, the Heller study?
- 22 A. So Heller found talc in women's
- <sup>23</sup> ovaries. Yes. Cramer found talc in pelvic lymph
- 24 nodes. We have other animal and human studies of
- 25 talc or particulates similar in size to talc

- 12 few minutes ago?

- A. The 2005, yes.
- 14 Q. This is 2007.
- 15 A. I'm sorry. Did I say 2005? Yes. This
- 16 is the paper, anyway.
- 17 Q. And the authors are Dan Cramer and Bill
- <sup>18</sup> Welch, Ross Berkowitz, and John Godleski. 19
  - Do you see that?
- 20 A. Yes.
- 21 Q. And three of those individuals have
- been disclosed as plaintiffs' experts in the talc
- 23 litigation. 24
  - Were you aware of that?
- 25 A. I was not aware of Bill Welch. I knew

- <sup>1</sup> after -- at some point, I was aware that
- <sup>2</sup> Dr. Cramer and Dr. Godleski was. I don't believe
- <sup>3</sup> I was aware of that at the beginning of my
- <sup>4</sup> research, but I became aware of that. Yes.
- Q. Okay. Are you aware that Dr. Welch has
- <sup>6</sup> been designated in maybe three cases and given
- testimony in those cases?
- A. Again, I was not aware that Bill Welch
- had been retained.
- Q. Are you aware that Dr. Welch has run 11 the pathology portion of Dr. Cramer's study
- 12 program for 40 years?
- 13 A. I'm aware who Dr. Welch is, and I've
- <sup>14</sup> certainly seen his name on papers. But now
- 15 his -- his role in these studies specifically, I
- <sup>16</sup> don't know if I can speak to other than he's
- <sup>17</sup> involved.
- Q. He's testified that his only role was
- <sup>19</sup> in identifying the types of tumors involved in
- <sup>20</sup> the study to keep people honest.
- 21 Are you aware that Dr. Welch has repeatedly
- <sup>22</sup> refused to give -- refused to give a causation
- opinion like you're giving today?
- A. I'm not aware of Dr. Welch's opinions.
- <sup>25</sup> I didn't know that he was an expert, so I

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- A. I'm sorry. Where are you now?
- Q. Same sentence. He just finishes it
- with "Many subsequent studies found --
  - A. Okav.
- Q. -- "talc use to increase the risk for
- ovarian cancer."
- But he just cites himself again from 1982;
- correct?

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12

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- A. Sorry?
- Q. The only cite he provides for that
- statement is his own study from 1982?
  - A. Oh, the one -- the No. 1?
  - O. Mm-hmm.
- 14 A. Yes. That's his 1999, it says. 1999.
  - Q. Okay. Sorry about that. You're right.
- 16 And then he says, "However, the causality of
- the relationship has been challenged for several
- reasons."
- 19 Do you see that?
- 20 A. I do.
- 21 Q. And he says, "First, the association is
- a relatively weak one; i.e., summary relative
- risk of approximately 1.3."
- Do you agree that a summary relative risk of
- <sup>25</sup> 1.3 is a weak association?

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- <sup>1</sup> wouldn't have reviewed any of that testimony.
- O. Okay. You weren't provided with any of
- <sup>3</sup> his testimony or his reports in the litigation? A. No. I was not aware that he was a
- <sup>5</sup> medical expert witness.
- Q. Okay. Do you see under the
- <sup>7</sup> "Background" section here, it says, "Although
- 8 epidemiologic studies suggest talc may increase
- <sup>9</sup> ovarian cancer risk, there is no proof that talc
- <sup>10</sup> used externally reaches the pelvis"?
- 11 A. That's what it says.
- 12 Q. Are then if you look down in the -- I'm 13 sorry. I'm sorry.
- If you look down in the first paragraph, he
- <sup>15</sup> mentions, "An epidemiologic association between
- 16 the use of cosmetic talc and genital hygiene and
- ovarian cancer was first described in 1982."
- 18 That's Cramer citing Cramer; isn't it?
- 19 A. Let's see. Let me double-check. I'm
- <sup>20</sup> assuming because it's 1982. But let me
- <sup>21</sup> double-check. Or -- yeah. It's 1999. He's
- <sup>22</sup> referencing his 1999 paper.
- Q. And he says, "And the many subsequent
- 24 studies found talc use to increase the risk for
- <sup>25</sup> ovarian cancer."

A. I've seen "weak" or "moderate" used to

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- <sup>2</sup> describe a 1.3, but that doesn't mean it's not a
- significant one, especially in a rare disease
- <sup>4</sup> like ovarian cancer.
- MS. AHERN: Objection to the
- nonresponsive portion.
- Q. But I agree it's been described as
- "weak," at least here by Dr. Cramer?
- A. That's -- the sentence says, "First,
- the association is a relatively weak one; i.e.,
- summary relative risk of approximately 1.3."
- 12 Q. And he says, "Second, there's no clear
  - increase in risk with duration of use."
  - Do you agree with that, as of 2007, there
  - was no clear dose-response in the studies that looked at talc and ovarian cancer?
- 17 A. I think there was evidence of a
- dose-response by 2007. 19 Q. So do you disagree with Dr. Cramer's
- statement in the 2007 publication that as of that
- 21 time, there was no clear increase in risk with duration of use in most studies?
- 23
- A. I wouldn't necessarily phrase it that <sup>24</sup> way: There's no clear increased risk. I think,
- <sup>25</sup> again, there isn't a lot of data, but what data

- <sup>1</sup> there was -- I believe at that time, I'm trying
- <sup>2</sup> to think if I was in 2007 -- would be evidence
- <sup>3</sup> that there was a dose-response.
- Q. And which papers, prior to 2007, did
- <sup>5</sup> they find dose-response that was clear?
- A. I would have to look back.
- 7 Okay. So I tried to do this in chronologic <sup>8</sup> order.
- 9 Q. What page are you on?
- 10 A. I'm looking at 16.
- 11 Q. Page 16 of Exhibit 14?
- 12 A. Yes.
- 13 Q. Okay. Were --
- 14 A. I'm just trying to refresh my memory.
- 15 So Harlow's -- let's see -- 1992 study was,
- <sup>16</sup> it looks like, the first one that I have listed
- <sup>17</sup> that had a dose-response -- evaluated for
- dose-response.
- 19 They both -- let's see. The confidence
- <sup>20</sup> intervals all included the null. Life- -- so
- 21 what I wrote here -- this is Page 18 -- "lifetime
- <sup>22</sup> application ORs when compared to control women
- with no perineal talc exposure were 1.3, 4 less
- 24 than 1,000, with a confidence interval of 0.7 to
- <sup>25</sup> 2.7; 1.5 for 1,000 to 10,000 with a confidence
- <sup>1</sup> interval of 0.9 to 2.4; and 1.8 for greater than
- <sup>2</sup> 10,000 with the confidence interval of 1.0 to
- 3 3.0.
- And then I also -- yeah. So that's after
- <sup>5</sup> 2007, the Terry and the Lou studies.
- Q. You're looking at Harlow 1992?
- 7 A. Yes. That's the paragraph I'm looking
- 8 at.
- 9 O. And Harlow 1992 found a
- 10 nonstatistically significant increased risk; is
- 11 that correct?
- 12 A. So the confidence intervals included
- 13 the null. So, yeah, it was not statistically
- 14 significant. I'm not sure -- I don't have the
- 15 numbers here, though, of how many they had
- 16 dose-response data on, which would -- which might
- <sup>17</sup> increase the interval.
- 18 In fact, if you look at the confidence
- 19 intervals, they're pretty wide, trending toward
- <sup>20</sup> higher.
- 21 Q. What are the confidence intervals
- 22 you're looking at?
- 23 A. For less than 1,000 lifetime
- <sup>24</sup> applications, we're looking at 0.7 to 2.7.
- 25 For 1,000 to 10,000, we're looking at 0.9 to

1 2.4.

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And for greater than 10,000, we're looking

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- at 1.0 to 3.0.
- Q. And when they just adjusted -- when
- they excluded -- when they looked at lifetime
- <sup>6</sup> talc applications and ovarian cancer after
- <sup>7</sup> excluding use following hysterectomy or tubal
- ligation, they found no evidence of an
- exposure-response relationship, didn't they?
  - A. Are you looking at the actual paper?
  - Q. Do you need it?
- 12 A. If you're asking me questions about it.
- Q. Yeah. That wasn't in your report -- or is it? 14
- 15 MR. ROTMAN: What is the "it" referring 16 to?
- 17 Q. That particular finding is not in her
- report on dose-response from Harlow in 1992?
  - A. Well, yeah. Let me look at the --
- 20 MS. AHERN: Sure.
  - (Article entitled "Perineal
- 22 Exposure to Talc and Ovarian Cancer Risk"
- 23 marked Exhibit 20.)
  - MS. AHERN: I'll mark as Exhibit 20 to
- <sup>25</sup> your deposition "Perineal Exposure to Talc and

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- <sup>1</sup> Ovarian Cancer Risk" by Harlow, 1992. That's my
- <sup>2</sup> only copy. Sorry.
- MR. ROTMAN: Exhibit 20.
- A. Okay. So, I'm sorry, where are you
- looking?
- Q. Let me find it. Take your time, if you
- need to. I'm trying to find my copy.
- Okay. If you look at Table 3, "Estimated
- total lifetime perineal applications of talc
- containing powders and cases and controls."
  - A. Okay. I see Table 3.
  - MR. ROTMAN: Is there a question?
- 13 MS. AHERN: She asked to see the study.
- I asked her to confirm that once they excluded
- cases after hysterectomy or tubal ligation, there
- was no exposure-response relationship.
- A. These look to be similar -- oh, I see.
- <sup>18</sup> Okay. Total applications.
- 19 Well, if you actually look at the numbers,
- <sup>20</sup> the ones above, which are, I believe, what I
- quoted in my report, so under "Total
- applications."
- 23 And then you're asking me about applications
- excluding use after hysterectomy or tubal
- 25 ligation?

- <sup>1</sup> BY MS. AHERN:
- Q. Mm-hmm.
- <sup>3</sup> A. What was your question about it? I'm <sup>4</sup> sorry
- <sup>5</sup> Q. There's no statistically significant
- 6 dose-response relationship with lifetime
- <sup>7</sup> application?
- 8 A. So the confidence intervals are
- 9 somewhat similar, but -- are somewhat similar, it
  10 looks like, to the top.
- Q. There's no statistically significant
- dose-response relationship, is there?
- A. They all include the null. That's correct. But, again, they're trending high.
  - Q. But if they include the null, then it's consistent with the null hypothesis that there's no association; isn't that true?
- MR. ROTMAN: Objection.
- A. It's possible. The null hypothesis is included in "Possibilities."
- Q. It also basically means you can't exclude chance as a reason for the findings;
- <sup>23</sup> correct?
- A. Again, it's possible. I would say it's trending higher, but it does include the null

- 1 dose-response?
- A. Well, I state in my report what the
- <sup>3</sup> confidence intervals are. So certainly, I'm
- 4 showing that it did include the null hypothesis.
- <sup>5</sup> But I think it's still -- just because it's not
- 6 statistically significant, I think it's still
- <sup>7</sup> data, and I wouldn't completely discount it.
- But it does -- does contain the null. The
- <sup>9</sup> numbers weren't super high, if I remember. But
- on their -- I'll have to find it.
- On -- in their abstract conclusion, they
- 12 still say that "The greatest ovarian cancer risk
- 13 associated with perineal talc use was observed in
- 14 the subgroup of women estimated to have made more
- than 10,000 applications during years when they
- were ovulating and had an intact genital tract
- with the OR of 2.8 and a statistically
- significant confidence interval of 1.4 to 5.4.
- 19 However, this exposure was found in only
- 20 14 percent of the women with ovarian cancer."
- Q. Okay. But we were just asking -- you
- 22 mentioned the study as support for a
- 23 dose-response relationship in your report?
  - 4 A. As evidence of a dose -- a
- dose-response; again, with the caveat, which is

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- <sup>1</sup> hypothesis.
- Q. Do you see on Page 25, in the first
- <sup>3</sup> column on the left-hand side, the first full
- <sup>4</sup> paragraph, "In our analysis"?
- Okay. The authors say, "In our analysis, we
- <sup>6</sup> first calculated all genital applications of talc
- <sup>7</sup> based on frequency and years of use. As a
- <sup>8</sup> continuous variable in a multivariate model, no
- <sup>9</sup> significant dose-response was observed between
- <sup>10</sup> total genital applications of talc and ovarian
- <sup>11</sup> cancer risk"; correct?
- 12 A. That's what it says.
  - Q. And the reason they excluded
- 14 hysterectomy and tubal ligation is the next
- <sup>15</sup> sentence, "because the translocation theory
- <sup>16</sup> assumes an open genital tract, we then excluded
- <sup>17</sup> application after tubal ligation or hysterectomy
- <sup>18</sup> but observed no appreciable change in the
- <sup>19</sup> dose-response."

22

- In other words, still no significant
- <sup>21</sup> dose-response; correct?
  - A. That's what it says.
- Q. So the authors interpreted both the
- <sup>24</sup> data you cite in your report as well as the data
- <sup>25</sup> you didn't cite in your report as showing no

- <sup>1</sup> here, that it includes the null hypothesis.
- Q. Okay. And what about Cramer in 1999?

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- 3 MR. ROTMAN: Objection. I don't think
- 4 that's a question.
- 5 MS. AHERN: Fair point.
- 6 BY MS. AHERN:
- Q. In Cramer 1999, you've also cited as
- 8 evidence after dose-response, correct, on Page 35
- <sup>9</sup> of your report?
- A. I see that. Yes. It's listed in a
- 11 reference list.
- Q. And the authors, including Cramer,
- <sup>13</sup> basically say they "failed to demonstrate
- <sup>14</sup> consistent dose-response relationships with
- measures of intensity of exposure."
- MR. ROTMAN: Do you have -- do you have the paper?
- MS. AHERN: Do you want the paper?
  - MR. TISI: Is that the one you
- <sup>20</sup> identified before?
- MS. AHERN: No. This is a new one.
- MR. ROTMAN: She's getting the paper
- 23 out.

- MS. AHERN: I thought I had it too.
- 25 Maybe it's in one of the boxes. Let me see if I

Page 268 Page 266 <sup>1</sup> can find my own copy. <sup>1</sup> in the table. Let me see. 2 Okay. Sorry. This is the only copy I Q. I think so. If you want to go to --<sup>3</sup> have right now. A. Oh. THE WITNESS: Okay. Q. You got it. A. Yes. I see it now. Sorry. It was MS. AHERN: We can mark it, if you 5 <sup>6</sup> buried in Table 3, very small print. Okay. Yes. 6 want. So Table 3, years of use. Yup. BY MS. AHERN: Q. It's a copy of the Cramer 1999 Q. Do you see they're not showing a publication that you cited in your report in <sup>9</sup> statistically significant dose-response support of dose-response. relationship? 11 MR. TISI: Are you marking it? 11 A. So for less than 20 years, the 12 THE COURT: I can if you want me to. I 12 confidence intervals were 1.16 to 3; at 20 and 30 13 just didn't want to mark my copy. and greater than 30, they did -- the confidence 14 MR. KLATT: I don't think I do. intervals did include the null. 15 MS. AHERN: That's all right. I don't. But, again, I don't know how many -- I can't <sup>16</sup> We'll mark Cramer -- oops, no, we won't because remember. Oh, here are the cases. <sup>17</sup> this is the wrong study. Sorry. The old "wrong Yeah. So there are 55, less than 20 cases; study" trick. thirty-two 20 to 30; and 59 greater than 30. 19 19 THE WITNESS: I can't find that Q. And you see also the frequency <sup>20</sup> analysis? It also did not find a significant <sup>20</sup> information. Oh, I've got the wrong reference. Sorry. All righty. dose-response relationship as a statistically 22 significant dose-response relationship? (Article entitled "Genital Talc 23 Exposure and Risk of Ovarian Cancer" marked A. Yes. For less than 30 years, the 24 Exhibit 21.) <sup>24</sup> adjusted OR was 2.21 with a confidence interval <sup>25</sup> of 1.37 to 3.56. 25 Page 267 Page 269 The 30 to 39 was adjusted OR of 1.17 with <sup>1</sup> BY MS. AHERN: Q. Okay. So, Doctor, this is Exhibit 21,

<sup>3</sup> which is "Genital Talc Exposure and Risk of

<sup>4</sup> Ovarian Cancer," Dan Cramer, 1999.

5 A. Okay.

6 Q. This is something else.

Can you find -- I don't have it in front of

me, so I'm going to rely on you to find the

tables that show their dose-response analysis. 9

10 MR. ROTMAN: You made that Exhibit 21?

11 MS. AHERN: Yes.

12 MR. TISI: It's 21. Yes.

13 THE WITNESS: Would that be Table 2,

<sup>14</sup> what you're referring to (indicating)?

15 BY MS. AHERN:

16

Q. I believe the numbers were -- they were

17 looked at in terms of zero years' duration, less

<sup>18</sup> than 20, 20 to 30, and greater than 30.

19 Do you see that on there?

A. I'm looking. This one says "less 20

21 than -- frequency of use."

Q. There's a frequency and a duration. 22

23 A. Okay.

24 Q. Yeah.

25 A. Sorry. Why am I not seeing it? It's

confidence intervals .78 to 1.76.

And the 40-plus adjusted OR was 1.57 with

confidence intervals of 0.8 to 3.10.

Q. So not only did the point estimate go

down with more use, but the higher the

concentration, there was also no statistical

significance; correct?

A. Yeah. I mean, the numbers -- so the

only one that doesn't include the null -- let me

just double-check.

12 Actually, there are two. So the less than

20 years or less than 30 per month are

statistically significant.

15 Q. It's only the first dose category in

16 each group --17

A. Yeah.

18 Q. -- shows statistical significance.

19 And as the doses got higher, the exposure

frequency got higher, the point estimates went

down and statistical significance went away;

22 correct?

23 A. The confidence intervals did include

the null. And I think this illustrates how

<sup>25</sup> difficult sort of dose and frequency can be to

Page 272 Page 270 <sup>1</sup> study because we don't really know what the doses <sup>1</sup> "application of talc." <sup>2</sup> are, and we don't really have granularity as far "Another factor that may affect the <sup>3</sup> as frequency of use. Well, I have to look at --<sup>3</sup> dose-response relationship is whether use Q. These are studies that you cited in 4 occurred at a time when the female tract was <sup>5</sup> your report as evidence of a dose-response, open. There is evidence from several studies <sup>6</sup> correct, the Harlow and the Cramer papers? You <sup>6</sup> that the talc/ovarian cancer association is <sup>7</sup> both cited yourself. modified by closure of the female tract as a Did you evaluate the internal validity of result of tubal ligation or hysterectomy. <sup>9</sup> those studies and critically evaluate the methods Q. Doctor, did they say they didn't find a <sup>10</sup> and study populations when you included them in dose-response relationship? 11 your report? 11 A. I'm trying to find what they said other 12 than that on Page 355. 12 A. Let me -- well, I said -- this is the 13 13 sentence -- "Most have found an increased risk of Yeah. They said, "Studies that have <sup>14</sup> ovarian cancer with increased exposure." So, dose-response, including this one, have failed to 15 yet, when studies have evaluated duration of demonstrate consistent dose-response <sup>16</sup> frequency of perineal talc use. relationships." So this list is the studies that evaluated But it goes on to qualify with the <sup>18</sup> duration and frequency of perineal talc use. And difficulty of measuring dose and frequency, which <sup>19</sup> I said, "Most have found an increased risk." So is what I described earlier. 20 20 what I'm citing here are the studies that looked Q. Mm-hmm. 21 at duration and frequency. 21 (Article entitled "Perineal Talc 22 Q. Okay. And we were referring to 22 Exposure and Epithelial Ovarian Cancer Risk 23 in the Central Valley of California" marked <sup>23</sup> Cramer's 2007 publication where he himself says <sup>24</sup> that the association has been challenged because 24 Exhibit 22.) 25 25 it's weak and because there's no clear increase Page 271 Page 273 <sup>1</sup> in risk with duration of use. <sup>1</sup> BY MS. AHERN: And you didn't agree with that statement, O. Okay. The next one -- are you done, <sup>3</sup> and you referred me to Harlow 1992; correct? sorry, with that one? A. I was going to where I mentioned the A. If we're moving on, sure. <sup>5</sup> dose-response studies. Q. If you're done. Q. Okay. Just to button up and finish up The next one you mention, you cite in your <sup>7</sup> with Cramer 1999, if you look at Page 355, the report for dose-response is Mills 2004, which I'm authors included, "They failed to demonstrate handing you now marked as Exhibit 22. <sup>9</sup> consistent dose-response relationships with 9 Oh, yeah. We'll leave that here for right 10 measures of intensity of exposure." 10 now. 11 Do you see that? 11 A. Okay. 12 A. I'm sorry. Where are you? 12 MR. ROTMAN: Can I see the one you just 13 O. On Page 355. 13 finished with? A. Okay. I'm seeing "in attempting" --MR. TISI: This is 22; right? 15 sorry. I see, "Most talc and ovarian cancer 15 MS. AHERN: Yes, sir. <sup>16</sup> studies that have addressed dose-response, BY MS. AHERN:

17

25

<sup>17</sup> including this one, have failed to demonstrate

20 especially when the trend is examined among users

21 only. In attempting to address this weakness, we

<sup>23</sup> amount of powder actually used and degree of

18 consistent dose-response relationships with

19 measures of the intensity of the exposure,

22 point out that it is difficult to quantify the

Do you see that?

23 compared to never users. However, no

Q. And this one, you're welcome to read

through it if you want. All I wanted to point

abstract, a little more than midway down, they

22 1.37 with the confidence interval of 1.02 to 1.85

out is if you look right up front in the

21 say, "The odds ratio for ever use of talc was

- A. I see where it says that.
- Q. And if you want to look through there
- <sup>3</sup> and convince yourself of that, go for it. I
- 4 think the table that we're looking at is Table 2 <sup>5</sup> on Page 460.
- A. Yeah. The 4 to 12 years had an OR of
- <sup>7</sup> 1.86 that was statistically significant at 1.16
- 8 to 2.98. But the others, which were never --
- <sup>9</sup> which, of course, is the null, 4 to 12 years,
- <sup>10</sup> which -- oh, the 13 to 30 was adjusted OR of
- 11 1.45, confidence interval .9 to 2.32.
- And then the greater than 30 years was OR of
- 13 1.22 with confidence interval of .72 and 2.08.
- <sup>14</sup> So the 13 to 30 and the greater than 30 includes
- 15 the null.

1

- 16 And then if we look at frequency, cumulative
- <sup>17</sup> use, frequency types duration, there was a
- <sup>18</sup> statistically significant increase with second
- <sup>19</sup> quartile and third quartile divisions. But then
- <sup>20</sup> it dropped in the fourth quartile, the highest
- <sup>21</sup> exposure.
- 22 And, you know, again, sort of difficulty in
- 23 measuring this. But you do see an increase in
- <sup>24</sup> the second and third quartile, between the second
- <sup>25</sup> and third, that was statistically significant.

- <sup>1</sup> And then --
- Q. But the authors themselves interpret
- <sup>3</sup> their data as no dose-response association;
- 4 correct?
- A. In the abstract, that's what they
- <sup>6</sup> state. I'm trying to figure out what their --
- <sup>7</sup> what they said. They must have said a little bit
- <sup>8</sup> more.
- 9 Q. Doctor, you reviewed this study before;
- 10 right?
- 11 A. I did. Yes.
- 12 Q. Okay.
- 13 A. I'm just refreshing my memory.
- 14 Q. Okay. If you look at Page 463.
- 15 MR. ROTMAN: Are you changing the
- 16 topic?
- 17 MS. AHERN: No. Same topic.
- 18 MR. ROTMAN: She was looking for
- something as part of a prior answer.
- BY MS. AHERN:
- 21 Q. As part of your prior answer that there
- <sup>22</sup> was no dose-response?
- 23 A. As part of the answer that they stated
- <sup>24</sup> that in the abstract. I was trying to find out
- <sup>25</sup> where they had a discussion.

- Q. I was trying to point you a little bit
  - <sup>2</sup> toward this. It's Page 463. There's some
  - <sup>3</sup> discussion of it.
  - If you look at the third paragraph down, "As
  - <sup>5</sup> in other studies, the present study did not find
  - <sup>6</sup> a clear dose-response based on duration of use or
  - cumulative use."
  - And then it says, "Limiting the analysis of
  - dose-response to women who reported ever use of
  - <sup>10</sup> talc did not affect the results, data not shown.
  - 11 The lack of dose-response between talc use and
  - <sup>12</sup> epithelial ovarian cancer may be explained by the
  - 13 inability to quantify the actual amount of talc
  - <sup>14</sup> used per application and the timing of the
  - application."
    - A. Yeah. So with that caveat.
  - 17 Q. Well, the findings are what they are;
  - 18 right?

16

- 19 The findings are no dose-response
- 20 relationship?
- A. The findings are what they are. But,
- again, it's not an easy -- there's not huge
- numbers in these cases.
  - And, again, you still don't know from woman

Page 277

- 25 to woman what one dose is, so there's a ton of
- Page 275
- <sup>1</sup> variability. It's not like a cigarette, where,
- <sup>2</sup> you know, from one cigarette to the next or, you
- 3 know, a drug dose is probably a more accurate
- <sup>4</sup> analogy, you know.
- Q. True. But just because it's difficult
- 6 to study, it doesn't mean if we could study it
- better, we would get a positive result, does it?
- A. I -- oh, my thing is not working. I
- think I have to plug my thing in.
  - MR. ROTMAN: Can you?
- 11 COURT REPORTER: I'd have to break to
- 12 do it.

10

- MR. ROTMAN: Let's go off the record.
- THE VIDEOGRAPHER: Off the record.
- 15 4:37 p.m.
- 16 (A recess was taken.)
- 17 THE VIDEOGRAPHER: Back on the record,
- <sup>18</sup> 4:44 p.m.
- 19 BY MS. AHERN:
- Q. Okay. Doctor, you saw the Mills paper
- 21 in front of you?
- 22 A. Yes.
- 23 Q. Okay. Could you look at your report on
- 24 Page 21?
- 25 (Witness complies.)

<sup>1</sup> A. Okay.

- Q. Let's see, where is my copy?
- And turn to Page 3 of the Mills publication.
- 4 A. Page 3, which would be Page 460?
- <sup>5</sup> Q. That's a good question.
- Where is my Mills publication?
- MS. AHERN: Do you have it?
- 8 MR. TISI: Sure.
- 9 MS. AHERN: Thank you.
- Oh, I know where it is.
- 11 BY MS. AHERN:
- Q. I'm sorry. I thought I had the
- 13 specific passage marked. And I do, somewhere in
- <sup>14</sup> here. Okay. Sorry. It's on Page 460. I
- <sup>15</sup> apologize.
- 16 A. Okay.
- Q. All right. Do you see on the Mills
- <sup>18</sup> publication on Page 460 that bottom paragraph on
- <sup>19</sup> the left, "ever use of talcum powder"?
- <sup>20</sup> A. Yes.
- Q. And if you read down toward the bottom
- <sup>22</sup> part of that paragraph, on the fourth line from
- 23 the bottom, the sentence starts "Duration of
- 24 use."
- A. Okay.

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- Q. "Duration of use of talcum powder was
- <sup>2</sup> associated with increased risk, although the
- <sup>3</sup> pattern was also not clear-cut in that the point
- <sup>4</sup> estimate peaked among those reporting 4 to 12
- <sup>5</sup> years of use and declined somewhat among those
- <sup>6</sup> reporting longer duration of use."
  - Do you see that statement?
- <sup>8</sup> A. I see that. Yup.
- <sup>9</sup> Q. And if you look at your report on
- $^{10}\,$  Page 21, the top paragraph, about midway, a
- 11 little -- well, a third of the way down, you pick
- 12 up with "Duration of use of talc was also
- <sup>13</sup> associated with increased risk, although the risk
- 14 peaked."
- Do you see that statement?
- <sup>16</sup> A. Yes.
- Q. If you compare those statements, are
- 18 they almost identical with the exception of the
- 19 statement by Mills that the pattern was not
- 20 clear-cut?
- A. They are similar. This might have
- <sup>22</sup> been, like I described earlier, where, if I was
- <sup>23</sup> taking notes, some of the language might have
- <sup>24</sup> gotten incorporated, although I do have the
- <sup>25</sup> citation.

- Q. Is there a reason that that entire
- <sup>2</sup> portion of your report is copied identically from

Page 280

- <sup>3</sup> Mills except for the qualifier that the pattern
- <sup>4</sup> was not clear-cut for dose-response?
- <sup>5</sup> A. Well, I think it still has the same
- <sup>6</sup> meaning.
  - Q. Without the qualifier?
- 8 A. I think the qualifier is in the -- in
- <sup>9</sup> the data.
- O. Okay.
- A. I don't think I was -- I wasn't trying
  - 2 to make it sound anything different than what it
  - was. I think I was trying to report the data.
  - Q. Okay. All right. And, Doctor, if you
- <sup>5</sup> turn to Page 10 of your report, the section on
- <sup>16</sup> inflammation.
- 17 Are you there?
  - A. Yes.

18

21

- Q. You start on the second paragraph under
- <sup>20</sup> "Inflammation" discussing oxidative stress.
  - A. Okav.
- Q. Okay. Were you aware that a
- 23 significant amount of the section of your report
- <sup>24</sup> on oxidative stress is copied verbatim? More
- 25 than 60 percent of it, I think, is copied
  - Page 281
- vas 1 verbatim from Dr. Saed's 2018 publication?
  - A. Again, if the language is similar, it
  - <sup>3</sup> was not an intentional. I am citing him here, so
  - <sup>4</sup> it's -- you know, it's clear that those are the
  - 5 G you know, it's clear that those are the
  - <sup>5</sup> references. Again, it might have been due to
  - <sup>6</sup> note-taking, but the citation is clear.
  - Q. Do you ever take verbatim language out
  - <sup>8</sup> of another scientist's work and not set it off in
  - <sup>9</sup> quotation marks in your professional work?
    - A. I think I've cited the source here.
  - 11 It's -- so it's not -- again, it's not like I was
  - intentionally copying his words. It was, again,
  - probably an editing while I was taking notes, but
  - the citations are clear.
  - <sup>5</sup> O. Is your -- is the underlying
  - <sup>16</sup> understanding that you have related to oxidative
  - stress and inflammation drawn primarily from
  - <sup>18</sup> Dr. Saed's work?
  - A. No. I mean, oxidative stress and
  - <sup>20</sup> inflammation is something that we study -- that
  - <sup>21</sup> I've studied.

- Q. Have you ever published a study on
- oxidative stress or redox biology?

  A. I have not published on oxidative
- <sup>25</sup> stress.

Q. What sort of work as a pathologist have you done that incorporates redox biology?

A. Well, again, this is part of our
 medical training. Certainly in training to be a
 physician, that is something that we learn. And,
 you know, pathologists do quite frequently come

across inflammatory -- inflammation literature.

Q. Are you -- is it your position that the
 information in your report under "Inflammation"
 that discusses oxidative stress and redox biology
 is common knowledge among pathologists?

A. That oxidative stress and inflammation,
yes. I think -- yes. I think that's widely
accepted.

The specific information contained on

Q. The specific information contained on Pages 10 and 11 of your report that was drawn from Dr. Saed's work, is that information that is common knowledge?

The specific enzymes that are discussed, the research on these issues, is that specific information there common knowledge?

A. It's common knowledge that these types of cancer are associated with inflammation, and certainly oxidative stress is part of inflammation.

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<sup>1</sup> A. I did attribute -- I certainly cited

him in several places in this area. And, again,
 it was not an intentional copying. Again, it

4 might have just happened with my editing, but I

<sup>5</sup> certainly tried to cite everything that I was

<sup>6</sup> looking at in the proper place.

But I do believe that it's common knowledge that chronic inflammation can cause different types of cancer. This is not really new data.

Q. Dr. Saed says that it's new data.

A. In what respect, though? If we're talking about myeloperoxidase, yes. But I'm talking about oxidative stress and chronic inflammation with known association with certain types of cancer.

Q. So it's your testimony that the
 verbatim text that you used in the section from
 Dr. Saed's 2018 paper was appropriately cited and
 attributed to him?

MR. ROTMAN: Objection.

A. Again, I'm not sure it's absolutely verbatim, but I certainly cited him in every place that I was referencing.

Q. Okay. We'll just move on.
 (Highlighted copy of Dr. Kane's

Page 283

Q. Was this common knowledge to you before you reviewed Dr. Saed's 2018 publication?

A. Yes. I was just citing his report at this point.

Q. Are you aware you also cited his underlying citations in the same spots that he cited them?

A. That's possible because I reviewed his citations as I was reading his citations.

Q. Did Dr. Saed give you permission to copy his -- the language from his publication?

A. I wouldn't characterize it as"copying." I think it may be similar language,

<sup>14</sup> again, because I was writing as I was reading.

But I am certainly clearly citing his work andthe other citations.

Q. Do you agree that Dr. Saed's 2018
 paper is a compilation of his own synthesis and

review of the underlying articles that heincorporated into his paper, and do you think

21 it's appropriate for you to just lift the

<sup>22</sup> language from his paper and the citations that he

23 found and synthesized and put it in your report

and not attribute it to him with quotation marks?
 MR. ROTMAN: Objection.

expert report marked Exhibit 23.)

<sup>2</sup> BY MS. AHERN:

Q. Doctor, I've marked as Exhibit 23 to
 your deposition a highlighted copy of your report

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5 that shows the verbatim text that has been

6 carried over from various publications into your
 7 report.

If you turn to Page 10 and 11, you'll see
that the highlighted portions are copied directly

from Dr. Saed's work.

MR. ROTMAN: Do you have a copy for me to this exhibit?

MS. AHERN: Oh. I do. Sorry about that.

MR. ROTMAN: So we're at Page 10 and 16 11?

MS. AHERN: That's just for the Saed publication. And there's one in there that Saed was also on.

MR. ROTMAN: Does she have the Saed publication in front of her?

MS. AHERN: I can find it for you.

23 BY MS. AHERN:

Q. But my point is, are you aware that that -- that there's a significant portion of

<sup>1</sup> that section of your report that is just

<sup>2</sup> cut-and-pasted from Dr. Saed's work?

A. I don't believe -- again, it's -- it

4 wasn't intentional with the citations, and it

<sup>5</sup> could have happened with my note-taking or other

<sup>6</sup> suggested input. But, again, I cited -- I

<sup>7</sup> certainly cited him in that section.

<sup>8</sup> Q. Okay.

MR. TISI: Did you mark that?

MS. AHERN: Hmm?

MR. TISI: Did you mark that as an

12 exhibit?

MS. AHERN: Yes. I think it's 23.

<sup>14</sup> Sorry.

9

MR. TISI: That's okay.

MR. ROTMAN: Do you have the Saed in

17 front of you?

18 BY MS. AHERN:

Q. I think it's -- it wasn't intentional

<sup>20</sup> is your testimony, and it's probably just a

<sup>21</sup> result of your note-taking process; is that

22 correct?

A. Well, because I cited him specifically,

<sup>24</sup> certainly it wasn't intentional to be verbatim.

<sup>25</sup> And I'm not sure exactly the process, but

<sup>1</sup> biology and inflammation, are you?

A. I am not currently participating in a

<sup>3</sup> study of oxidative stress or redox biology.

Q. You don't have any funding related to

<sup>5</sup> oxidative stress and inflammation, do you?

A. No, I do not.

Q. Have you ever applied for any funding

8 in that area?

A. No. I have not.

Q. Have you ever authored a systematic

11 review of the literature on oxidative stress and

inflammation?

A. Oxidative stress and inflammation, no.

<sup>14</sup> I don't believe I have.

<sup>5</sup> Q. Have you ever authored a systematic

16 review of the literature on oxidative stress and

<sup>17</sup> cancer?

A. No. I have not authored a systematic

<sup>19</sup> review on that.

Q. Okay. Doctor, moving on to

<sup>21</sup> inflammation and ovarian cancer.

Generally, on inflammation, can you cite to

<sup>23</sup> a published experiment that was conducted in

<sup>24</sup> animals in vivo that establishes a role of any

<sup>25</sup> particular inflammatory cell or cytokine or

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<sup>1</sup> certainly I'm citing him several times there.

<sup>2</sup> Q. Okay. That's fine. We'll just move <sup>3</sup> on.

And, Doctor, just to be clear, I understand

<sup>5</sup> your testimony is that it is common knowledge to

<sup>6</sup> pathologists that oxidative stress and

<sup>7</sup> inflammation are related; correct?

8 A. Yes.

<sup>9</sup> Q. Okay. But you are -- we're talking

about oxidative stress and redox biology

<sup>11</sup> specifically as a field of study or research.

You're not an expert in that field of study

13 or research, are you?

A. I certainly have read literature in

15 that area.

16

Q. Does that make you an expert?

A. I'm -- I mean, I'm familiar with

18 literature in the area. That's -- that's my

<sup>19</sup> answer.

Q. Okay. But you don't conduct studies in

<sup>21</sup> oxidative stress and redox biology, do you?

A. I do not conduct studies in oxidative

23 stress and redox biology.

Q. You're not currently participating in a

25 study looking at oxidative stress or redox

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<sup>1</sup> enzyme in tumor regenesis?

A. Oh. Let me -- let me bring up my

<sup>3</sup> inflammation section. Sorry. I'm just

<sup>4</sup> refreshing myself as to what I stated in my

<sup>5</sup> report.

6 Oh, this is low battery again. I don't

<sup>7</sup> think this is plugged in.

8 MR. ROTMAN: Can we take five minutes

<sup>9</sup> off the record?

MS. AHERN: Yes.

11 THE VIDEOGRAPHER: Off the record,

<sup>12</sup> 5:02 p.m.

10

17

19

22

(A recess was taken.)

4 THE VIDEOGRAPHER: Here begins Media

No. 6 in today's deposition of Sarah Kane, M.D.

Back on the record, 5:28 p.m.

(Article entitled "Talcum

powder, chronic pelvic inflammation and

NSAIDs in relation to risk of epithelial

ovarian cancer" marked Exhibit 24.)

21 BY MS. AHERN:

Q. Dr. Kane, I'm marking what's been --

<sup>23</sup> well, I'm marking Exhibit 24 to your deposition,

which is a copy of the Merritt 2008 publication.

<sup>25</sup> And I'm sorry, I don't have an extra. I'm going

- <sup>1</sup> to share.
- It's "Talcum powder, chronic pelvic
- <sup>3</sup> inflammatory -- sorry, chronic pelvic
- 4 inflammation and NSAIDs in relation to risk of
- <sup>5</sup> epithelial ovarian cancer."
- And you cite Dr. Merritt's paper a couple of
- times in your report; is that correct?
- A. I believe I cited it, yes.
- 9 Q. I think you cite it as a statistically
- 10 significant positive talc study on Page 17 of 11
- your report?
- 12 A. Oh, let me get to that, if that's the
- <sup>13</sup> section I'm thinking of.
- 14 Q. There are a couple of places?
- 15 A. There was -- yes. This happened in
- <sup>16</sup> editing. I believe if this is -- so the sentence
- ended up, it originally didn't have the
- 18 "statistically significant." It was just, you
- 19 know, an odds ratio greater than one and listed.
- And then I mistakenly didn't delete. When I
- 21 changed it to "statistically significant," for
- 22 some reason -- I don't know if it happened in the
- 23 editing between additions or something -- somehow
- <sup>24</sup> I seem to remember deleting them. But in the
- 25 final, they ended up all there. So that was a --

- <sup>1</sup> of multiple publications.
  - A. Right.
- Q. You're saying that some of those
- publications shouldn't be in there because you

Page 292

Page 293

- added "statistically significant" as a criteria
- later?
- A. Exactly.
- Q. Okay. That's actually not my question
- about Merritt, but thank you.
  - A. I knew that was going to come up --
- 11 Q. That's okay.
- 12 A. -- at some point.
- 13 Q. While we're there, since we're sitting
- <sup>14</sup> here looking at this, so these are -- you listed
- out case-control studies addressing talc, and
- they're supposed to be those that have
- statistically significant odds ratios; correct?
  - A. That's correct. That was the
- 19 intention.
- 20 Q. And Gertig 2000 is there, and Houghton
- 2014 are there, and they're obviously cohort
- studies?
- 23 A. So, again, I think that somehow that
- paragraph got all -- and I didn't catch it in the
- <sup>25</sup> final edits.

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- MR. ROTMAN: What page was this?
- 2 A. -- typographical error.
- It's in there twice. I noticed it after I
- 4 submitted it, and it was one of those --
- Q. Are you saying Merritt is not
- <sup>6</sup> statistically significant?
- A. So I know which -- again, I'd have -- I
- 8 have to go through. It's been a long day, and
- <sup>9</sup> the names are starting to get all confused.
  - Q. Yeah.

1

10

16

- 11 A. But I know that that sentence, with
- 12 "all of those" at the end of that sentence, is
- 13 incorrect because I had changed -- I had meant to
- 14 list cumulatively the statistically significant
- 15 ones and ended up --
  - Q. Okay. So just to clarify for the
- 17 record, on Page 17, we're talking about the first
- <sup>18</sup> full paragraph that says, "In addition to the
- <sup>19</sup> Cramer 1982 study, numerous other case-control
- <sup>20</sup> studies addressing talc use and ovarian cancer
- <sup>21</sup> have shown statistically significant odds ratios
- <sup>22</sup> greater than one indicating talc use is
- <sup>23</sup> associated with an increased ovarian cancer
- 24 risk."
- 25 And then there's a string cite with a number

- Q. Okay.
- A. I know that that was at least a
- <sup>3</sup> different paragraph at first, possibly two
- paragraphs that got condensed. And then somehow,
- the references didn't get changed in the final.
- Q. Okay. Do you happen to know -- and if
- you don't it's okay -- but do you happen to know
- which of these studies should be there and which
- should be removed?
- A. Off -- I would want to look just to
- 11 make sure.

- 12 Q. Okay.
- A. But I'm -- if I am -- I'd want to look
- just to make sure, but I know there are some that
- should not be there.
  - Q. All right. But looking at Merritt,
- there are a couple of places where Merritt is
- cited in your report. One is Page 17 in that
- paragraph we just looked at. Another is Page 28
- 20 in Section -- the "Pooled study regarding talc
- 21 use and ovarian cancer" section.
- It says some -- let's see, you're talking
- <sup>23</sup> about the advantages of pooled studies, and you
- 24 cited Merritt 2008.
- 25 A. Okay.

Page 294 Q. And then on Page 35, Merritt is cited.

- <sup>2</sup> "Studies evaluating duration and frequency of
- <sup>3</sup> perineal use, most have found an increased risk
- <sup>4</sup> of ovarian cancer with increased exposure."
- We already went through this paragraph
- 6 earlier --
  - A. Yeah. Yeah. Q. -- and discussed Merritt a little bit
- in that context.
- MR. ROTMAN: Page 30 -- the last one
- 11 was Page 35?
- 12 MS. AHERN: Thirty-five. Yeah. I
- <sup>13</sup> apologize. We may not have discussed Merritt.
- 14 BY MS. AHERN:
  - Q. But looking at Merritt now, you're
- <sup>16</sup> aware that Merritt looked specifically at
- <sup>17</sup> inflammatory conditions as part of their
- <sup>18</sup> exploration of the hypothesis that chronic
- 19 inflammation could lead to ovarian cancer; is
- 20 that right?
- 21 A. Yes. There was a component from what I
- <sup>22</sup> remember.
- 23 Q. They say in the abstract that "Chronic
- <sup>24</sup> inflammation has been proposed as the possible
- causal mechanism that explains the observed
  - Page 295
- <sup>1</sup> association between certain risk factors such as
- <sup>2</sup> the use of talcum powder or talc in the pelvic
- <sup>3</sup> region and epithelial ovarian cancer."
- Do you see that? It's in the abstract, the
- <sup>5</sup> first sentence?
- A. Yeah. Okay. The first sentence.
- Q. Okay. They go on to say, "To address
- the issue, we evaluated the potential role of
- chronic local ovarian inflammation in the
- <sup>10</sup> development of the major subtypes of epithelial
- <sup>11</sup> ovarian cancer."
- 12 Do you see that?
- 13 A. Yes.
- Q. Okay. And just want to ask you: They
- <sup>15</sup> conducted the study as a case-control study
- looking at 2319 women with epithelial ovarian
- 17 cancer; correct?
- 18 A. I don't remember the exact number, but
- 19 I will -- I will --

20

- Q. I think that's -- that's okay.
- 21 A. I don't remember the exact number.
  - Q. Okay. So they looked at a number of
- <sup>23</sup> factors that are theoretically associated with
- chronic inflammation, didn't they, including
- pelvic inflammatory disease and talc use,

- <sup>1</sup> endometriosis.
- And do you see if you turn to -- I'm trying
- <sup>3</sup> to get through this quickly. You're welcome to
- point out anything you want, but I kind of want
- <sup>5</sup> to move us along.
  - A. Okav.
- Q. If you look at the "Discussion"
- section, I, unless I missed it, on Page 174, the
- right-hand column, second full paragraph, they
- note that "It has been hypothesized that talc is
- linked to ovarian cancer development through
- 12 inflammation. However, evidence linking an
- 13 inflammatory response with talc contamination of
- 14 the ovaries is lacking."
- Do you agree or disagree with that statement
- that evidence linking an inflammatory response
- with talc contamination of the ovaries is
- lacking?
- 19 A. I don't know if I would phrase it that
- <sup>20</sup> way. Have there been studies that have followed
- talc from application up to the ovaries and
- <sup>22</sup> documenting an inflammatory response after talc?
- No. There's not going to be that study.
- That would be -- I don't think you could do
- 25 that study today with talc being called by the
- Page 297

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- <sup>1</sup> IARC a possible carcinogen. I don't think you
- <sup>2</sup> could design that study right now and do that in
- <sup>3</sup> women.
- But, again, I think -- I think it's still a
- <sup>5</sup> highly compelling, plausible mechanism because we
- 6 know talc can cause inflammation, and
- inflammation is associated with certain cancers,
- including certain types of ovarian cancers.
- 9 So I don't know if I would state it that
- 10 way.
- 11 Q. When you say inflammation is associated
- 12 with ovarian cancer, what studies are you
- 13 referring to?
- A. I'm referring to, for example, clear
- cell carcinomas that have arisen from
- endometriotic lesions that we've talked about
- <sup>17</sup> before.
- 18 Q. And those cells are -- the originating
- cells are thought to come from the endometrium
- 20 itself, the uterus; correct?
- 21 A. I don't know if we know for sure. I
- 22 mean, is it endometriosis that's in the ovary
- causing chronic inflammation in the ovarian cells
- that are causing the clear cell? I don't know if
- that's been completely delineated.

- 1 O. But there are markers that will
- <sup>2</sup> distinguish ovarian surface epithelial cells from
- <sup>3</sup> endometrioid cells which resemble endometrial
- 4 cells: correct?
- A. There are some stains that you can do.
- 6 But, again, I don't know if it's going to be --
- been completely elucidated.
- Q. Are you aware of recent studies that
- <sup>9</sup> have demonstrated that there is some abnormality
- 10 in the endometrium of women who develop
- 11 endometriosis when compared to women who don't
- 12 develop endometriosis?
- 13 A. I'm aware that retrograde migration of
- 14 the endometrium is thought to -- has been
- 15 associated with endometriosis. I don't know what
- 16 you mean by "abnormalities" of the -- you have to
- <sup>17</sup> be more specific. I can't --
- Q. I don't have the publication with me.
- 19 I was just asking if you were aware of those
- <sup>20</sup> studies.
- 21 A. I probably read them at some point, but
- 22 off the top of my head, I'm not really sure
- without knowing more specifically.
- Q. And would you agree that the studies,
- though, that show a decreased risk of ovarian

<sup>1</sup> inflammatory mechanism in the development of

Page 300

- <sup>2</sup> epithelial ovarian cancer. However, experimental
- <sup>3</sup> evidence that perineal talc use elicits an
- 4 inflammatory response in the ovaries is lacking,
- <sup>5</sup> and overall, we conclude that chronic
- <sup>6</sup> inflammation does not play a major role in
- development of ovarian cancer."
- Is there a reason you didn't cite the
- Merritt study in your report specifically when
- discussing evidence of chronic inflammation and
- ovarian cancer, a link between those two?
  - A. In the places that I -- let me just
- 13 double-check. Places that I mention, was I
- not -- I wasn't talking about inflammation. Is
- that what you're --
- 16 Q. Yes. You agree you cited Merritt in
- several places in your report?
  - A. Yes.

12

- 19 O. But you didn't cite anything about the
- inflammation findings from Merritt.
  - A. I'm not sure I can completely agree
- with their conclusion. It's true we don't
- have -- like I mentioned before, we don't have a
- study that has looked at women who use talc,
- <sup>25</sup> follow it up, and then see chronic inflammation

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- <sup>1</sup> cancer for women who have tubal ligation are
- <sup>2</sup> studies -- well, are more highly associated with
- <sup>3</sup> endometrioid clear cell carcinomas than with
- <sup>4</sup> high-grade serous?
- A. With tubal ligation, off the top of my
- 6 head, I believe that's -- that that's the case.
- But with salpingectomy, which removes the
- <sup>8</sup> fallopian tube fimbriae, there's -- that
- decreases the risk of serous carcinomas.
  - Q. To a lesser extent, then, the decrease
- 11 for clear cell and endometrioid, which some
- 12 people have suggested supports the retrograde
- 13 migration of endometrial cells into the abdominal
- 14 cavity?

10

- A. Some people have said that that
- <sup>16</sup> supports the retrograde migration of the
- 17 endometrial cells. That is correct.
- Q. And I got off topic. We're looking at
- 19 Merritt. Page 174, if you look, let's see --
- <sup>20</sup> here it is. Sorry. I apologize, on Page 175.
- The very bottom of the summary paragraph, it
- 22 says, "The elevation in ovarian cancer risk
- 23 associated with use of talc in the perineal
- <sup>24</sup> region that we and others have observed has been
- <sup>25</sup> regarded as the main evidence supporting an

- Page 301 <sup>1</sup> in the ovary.
- But I think that's going to be -- again, we
- <sup>3</sup> don't know how long that chronic inflammation is going to be there. We don't know what dose is
- getting into the ovary.
- I still think -- and, again, this is the
- plausibility part of it -- I think there's still
- compelling evidence that talc can cause an
- inflammatory response that would explain the risk
- of increased risk of ovarian cancer with talcum
- 11 powder products.
- 12 So, I mean, I certainly read this. It had
- 13 some good information in it. I don't think I was
- purposely trying to leave out something that had
- evidence. This was their opinion.
- 16 And I'm -- I don't know if I would phrase it that way, the exact words that they use.
- Q. Well, if those are exactly their
- findings here -- if you look at the top of the
- summary paragraph, "In summary, most factors that
- could potentially cause ovarian inflammation such
- as pelvic inflammatory disease, HPV infection,
- and postpubertal mumps were not associated with a
- significant elevation in ovarian cancer risk in
  - our study. In addition, the expected corollary,

- $^{\scriptsize 1}\,$  an inverse association with regular use of
- <sup>2</sup> anti-inflammatory medications, was also not
- <sup>3</sup> observed -- or was not observed."
- A. Yes. Yeah. Yeah.
- <sup>5</sup> Q. They looked at multiple sources or
- <sup>6</sup> multiple causes of inflammation in the pelvic
- <sup>7</sup> region and did not find an association with the
- <sup>8</sup> risk of ovarian cancer, and they didn't find a
- <sup>9</sup> decreased risk in people that used
- o inflammatory -- anti-inflammatory medications.
- <sup>11</sup> A. I think I mentioned --
- <sup>12</sup> Q. So this is an inflammation study, isn't <sup>13</sup> it?
- A. Yeah. I think I mentioned in -- about
- 15 NSAIDs that I might have cited them in that
- section, that the evidence was not consistent
- <sup>17</sup> with NSAIDs, if I remember correctly.
  - I definitely looked at this paper when I was
- 19 looking at NSAID and aspirin use and certainly
- <sup>20</sup> inflammation as well. So...
- Q. It's actually not cited anywhere with
- <sup>22</sup> NSAID use or regarding inflammation at all.
- So maybe it was an earlier draft and was
- <sup>24</sup> removed at some point?
- A. It's possible.

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- Q. And you also -- you cite -- you do cite
- <sup>2</sup> some of the NSAID studies and aspirin studies,
- <sup>3</sup> but you leave out others. You leave out Baandrup
- 4 2013, which was a negative study; Bonovas, 2005,
- <sup>5</sup> which was a negative study; Ni, 2012, which was a
- 6 negative study.
- When you did your review of inflammation
- 8 including anti-inflammatory medications and the
- <sup>9</sup> risk of ovarian cancer, did you pull out more
- 10 studies in review than you actually included in
- 11 your report?
- 12 A. Yes. There are definitely more studies
- <sup>13</sup> than were cited in my report.
- Q. Is there a reason you didn't cite the
- 15 negative studies?
  - A. I didn't intentionally leave out the
- negative studies, but I do mention that the
- <sup>18</sup> evidence had been inconsistent with NSAID.
- Q. Okay. And you mentioned the Heller
- 20 study in a couple of places. You mentioned
- 21 several times that part of your plausibility
- 22 opinions involve the fact that talc has been
- 23 observed in the ovaries; correct?
- A. Can you show me? I'm sorry. I just
- <sup>25</sup> want to make sure.

- <sup>1</sup> Q. I'm sorry. I'm just referring
- <sup>2</sup> generally.
- Do your opinions, in part, depend on the
- 4 finding of talc in ovaries?
- 5 A. No. Because I think, again, it's
- <sup>6</sup> difficult to find talc in the ovaries. So I
- <sup>7</sup> would not expect to see -- to find, to
- 8 histologically find talc in every ovary of a
- <sup>9</sup> woman who has used talcum powder products. I
- think that would be extremely difficult to do in
- 11 every patient.
- And I know we talked about the MUC-1 theory
- <sup>13</sup> earlier, but if that is the mechanism, that would
- 14 not require talc to get to the ovary.
  - So, no, I don't think it's necessary to find
- talc in the ovary in every woman to come --
- <sup>17</sup> that's a user.
  - Q. Let's talk about evidence for
- <sup>19</sup> talc-induced inflammation in the ovary.
- For instance, you've cited the Heller study
- 21 from 1996 in your "Migration translocation,
- <sup>22</sup> inhalation, and lymphatic transport" section on
- <sup>23</sup> Page 14.

25

- A. Mm-hmm.
  - Q. Heller actually states in their study

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- <sup>1</sup> that they did not find on their H&E slides any
- <sup>2</sup> response -- any expected response to talc
- <sup>3</sup> particles.
  - Do you remember that?
    - A. I do remember that vaguely. Yes.
- 6 Q. Did any of the studies that you cite in
- <sup>7</sup> that section for the proposition that talc has
- <sup>8</sup> been found in ovarian tissue, did any of those
- <sup>9</sup> find a reaction to talc in the ovaries?
  - A. I don't believe the studies that have
- 11 found talc in the ovaries have all looked for
- 12 chronic inflammation. Some of them, if I'm
- 13 remembering correctly, I don't know if they all
- looked histologically; but the ones that did, I
- <sup>15</sup> don't believe they had mentioned finding chronic
- <sup>6</sup> inflammation near the talc particles.
- But again, you know, depending on how long
- that inflammatory response is going to be there, depending how long that particular talc particle
- has been there, you wouldn't necessarily expect
- 21 to still see it 20 years later.
  - Q. Okay. In the Heller study, they looked
- 23 at ovarian tissue -- ovaries from one of their
- <sup>24</sup> subjects who had 1.7 or approximately
  - 5 1.669 million particles per gram of wet weight by

1

4

6

7

15

21

Page 306 <sup>1</sup> electron microscopy and found on hematoxylin and

- <sup>2</sup> eosin stain slides from the analyzed sections of
- 3 the tissue that no evidence of response to talc
- 4 such as foreign body giant cell reactions or
- <sup>5</sup> fibrosis in the tissue.
- Is that consistent with the other studies
- that have reported findings from H&E have also
- 8 reported no response to talc or supposed talc
- they found? 9
- 10 What is an alternative explanation for how
- 11 microscopists doing these sorts of studies might
- 12 find talc by TEM or SEM without any histologic
- 13 response --
- 14 MR. ROTMAN: Objection.
- 15 Q. -- to talc in the tissue?
- 16 A. Well, I think I addressed that a little
- <sup>17</sup> earlier. Again, I don't know -- we don't know
- 18 how long a chronic inflammatory response would be
- 19 there after a particular talc particle lands on
- 20 the ovary.
- 21 But the important thing would be that that
- 22 chronic inflammation, the initial chronic
- 23 inflammation, whenever that may be, however long
- 24 it is there, causes oxidative stress that induces
- <sup>25</sup> an oncogenic change in an ovarian cell or

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- <sup>1</sup> fallopian tube cell, for that matter.
- So -- and these are very small studies that
- 3 looked at histologic -- that looked
- <sup>4</sup> histologically for talc in these ovaries.
- So, you know, I don't necessarily think -- I
- 6 don't think that you would have to find chronic
- <sup>7</sup> inflammation if you're looking at an ovary at a
- 8 particular point in time when we're talking about
- <sup>9</sup> long-term talc use from, you know, up to 20 years
- <sup>10</sup> ago or something.
- 11 Q. Well, if they're finding 1.7 million
- 12 particles per gram of wet tissue right then and
- 13 there, and their slides from that time period
- 14 don't show any response whatsoever to talc that
- 15 they would expect to see, what's an alternative
- <sup>16</sup> explanation?
- 17 A. An alternative explanation is that
- 18 there was chronic inflammation, and it has since
- 19 resolved.
- Q. How about there might be contamination
- 21 of their samples with talc, which is ubiquitous
- <sup>22</sup> in many laboratories?
- 23 A. I believe they -- I have to look at the
- 24 study to -- do you have the study?
- 25 MR. ROTMAN: Thank you. What number?

- Page 308 MS. AHERN: What number are we on?
- 2 COURT REPORTER: Twenty-five.
- 3 MS. AHERN: Twenty-five.
  - MR. TISI: So 24 was --
- 5 MS. AHERN: We'll wait.
  - (Article entitled "The
    - relationship between perineal cosmetic talc
- 8 usage and ovarian talc particle burden"
- 9 marked Exhibit 25.)
- A. I believe they went through standard
- electron microscopy methods, which controls for
- contamination.
- BY MS. AHERN:
- 14 Q. How?
  - A. I don't know if it goes through the
- whole -- but they're very careful in how they
- handle tissue before they prep for electron
- microscopy.
- Q. Doctor, do you know where they got the
- 20 tissue from?
  - A. Yeah. It's listed.
- 22 Q. Did they collect the tissue themselves
- <sup>23</sup> from the patient in a particulate-free
- environment and handle it with particulate-free
- gloves in containers, or did they get it from
  - Page 309
- 1 hospital paraffin-embedded tissue?
- If you look on Page 1508, "Ovarian tissue in
- <sup>3</sup> blocks was reparafinized, rehydrated, blotted dry
- and weighed, and then digested with reagents."
  - A. So I think these women were talc users.
- <sup>6</sup> I'm trying to find controls that they had ovaries
- from -- if I remember correctly, they had ovaries
- <sup>8</sup> from fetal cases that did not show talc, if I
- remember correctly. I'm trying to find that.
- Yeah. "In addition, the ovaries of two
- stillborn fetuses were analyzed as negative
- 12 controls."
- 13 Q. Does it say anything about where those
- stillborn fetus ovaries came from and if they
- <sup>15</sup> were handled in the same hospital in the same way
- that the parafinized blocks were handled?
- 17 A. If they didn't have a separate section
- of their methods how they handled it, it would be
- the same methodology.
- 20 Q. Well, assuming it's not contamination
- and there's still no reaction to talc, another
- alternative explanation might be that talc
- doesn't cause chronic inflammation in the
- 24 ovaries.

25

A. But they didn't find talc in their

<sup>1</sup> negative controls, which were fetal females that <sup>2</sup> would never have been exposed to talc.

O. Except for after the tissues were taken 4 from the fetuses and processed?

A. I'm just trying to find where they --6 what they did.

Q. What I wonder and what I don't think is 8 in the paper, unless you can find it, is an <sup>9</sup> explanation for how the fetal ovaries were

10 obtained and processed. 11 Did they come from the same hospital 12 system --

A. It would be the same.

13

21

14 Q. -- from the laboratory so that any <sup>15</sup> contamination that occurred to those tissues prior to the Heller group getting them was accounted for?

Or did they purchase them separately through a company or something else that handled them <sup>20</sup> differently from the hospital samples?

MR. ROTMAN: Objection.

22 A. If those were obtained differently, it 23 should have been in the methodology. So the fact 24 that it's not there, the next sentence after they

25 say, "In addition, the ovaries of two stillborn

<sup>1</sup> something that would happen over days. Chronic

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<sup>2</sup> inflammation is generally longer, but it still

<sup>3</sup> resolves.

Q. And are -- for instance, pelvic

inflammatory disease is -- the effects of pelvic

<sup>6</sup> inflammatory disease can be seen by pathologists

for a very long time; correct?

A. You can see fibrosis. So...

Q. And one of the things that you

mentioned earlier is that talc can cause

11 fibrosis?

12 A. Talc can cause fibrosis. You get -- in

13 the ovary, however, you will get surface

fibrosis, generally, from the mesothelial cells

in the surface.

16 But, again, you're not always going to have fibrosis with chronic inflammation, either.

Q. If it's chronic inflammation that is

significant enough to lead to a transformative

event, shouldn't you expect to see some evidence

<sup>21</sup> of that chronic inflammation?

A. Well, we don't know how much chronic <sup>23</sup> inflammation is necessary to cause a carcinogenic effect.

Q. By analogy, wouldn't you look at

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<sup>1</sup> fetuses were analyzed as negative controls," that

<sup>2</sup> is where, if it had been a different methodology

<sup>3</sup> or different purchased ovarian cell blocks from

4 fetuses, which I have never -- anyway, it would

<sup>5</sup> be -- it would be there. And it's not.

Q. Hmm. So my next question is: I had <sup>7</sup> asked you earlier if there was an alternative

8 explanation for why there's no tissue response

<sup>9</sup> seen in this study to talc particles, and you

10 said it could be because the chronic inflammation

<sup>11</sup> was there and not there at the time that they

12 looked at the H&Es?

13 A. Yeah. I mean, you're looking at an 14 ovary at a very -- at one time point. So we

<sup>15</sup> don't know how long those talc particles were

16 there. We don't know if -- how long -- we don't

17 know how long the chronic inflammation is there.

But the important thing is that the chronic

19 inflammation would cause an event to change to an <sup>20</sup> oncogenic phenotype, gene type.

Q. So chronic inflammation is, by

22 definition, chronic; correct? Doesn't just -- it <sup>23</sup> doesn't just resolve in a couple of days.

24 It's ongoing; is that correct?

25 A. It is -- acute inflammation would be <sup>1</sup> something like ulcerative colitis and colon

<sup>2</sup> cancer since that seems to be a fairly

<sup>3</sup> well-established association?

A. Yes. And as soon as patients are

<sup>5</sup> diagnosed with ulcerative colitis and Crohn's

<sup>6</sup> disease, they are carefully followed at the

beginning. We don't wait 20 years to start

following them. We know that, you know, the risk

is there. As soon as they're diagnosed, we know

there is a risk for increased cancer, so we start

surveying them.

12 Q. But there's massive evidence of

13 inflammation -- tissue-damaging inflammation in

ulcerative colitis; correct?

A. Not always massive, but there's chronic 16 inflammation.

17 Q. Throughout the entire GI tract or

19 A. In -- it's not always the whole, but

yeah, there's chronic inflammation in the

<sup>21</sup> intestines.

22

25

Q. There's nothing in the literature that

suggests that talc causes that kind of an

inflammatory reaction, is there?

A. That talc causes a chronic

<sup>1</sup> inflammation?

- Q. That talc causes that sort of chronic
   inflammatory reaction.
- 4 A. Well, I showed you some excerpts where 5 they mention lymphocytic and plasmacytic
- 6 inflammation due to talc. We know that talc
- <sup>7</sup> causes an acute inflammation. I know we weren't
- 8 talking about acute inflammation, but we know it
- <sup>9</sup> causes acute inflammation in the -- after a
- $^{\mbox{\scriptsize 10}}\,$  pleurodesis. And I'm sure you could have
- 11 lymphocytes in plasma cells there too.
- Again, I don't think it's the -- sure. Theamount and duration of chronic inflammation, I
- mean, would that increase the risk? But even a
- small amount of chronic inflammation for a
- relatively short period of time, I think it'splausible.
- And, again, this is all under the plausible thing that this would cause a mutagenic effect.
- Q. Can you name other chronic inflammatory conditions that are not associated with cancer?
- 22 A. Chronic inflammatory conditions that
- <sup>23</sup> are not associated with cancer? Well, I'm not
- <sup>24</sup> sure we absolutely know every -- that a chronic
- <sup>25</sup> inflammatory condition won't cause a cancer,

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25

- $^{1}\,$  but -- so I'm not really sure. I'm not really
- <sup>2</sup> sure what you're getting at.
- Q. Can you list five chronic inflammatory conditions?
- A. That don't cause --
- Q. Just list five chronic inflammatory
   7 conditions.
- 8 A. Well, we have rheumatoid arthritis that
- <sup>9</sup> increases risk of lymphomas. We have
- <sup>10</sup> Helicobacter pylori infections that increase
- 11 gastric cancer. We have the ulcerative colitis,
- 12 Crohn's disease, that increase the risk of
- <sup>13</sup> cancer. Agent exposures like asbestos that
- <sup>14</sup> causes chronic inflammation and causes cancer.
- <sup>15</sup> HPV infection causes cancer. I mean...
- Q. Can you name one that doesn't involve a virus or an underlying immune dysfunction?
- <sup>18</sup> A. I named asbestos.
- <sup>19</sup> Q. Asbestos.
- 20 And was there another?
- A. Again, I don't know if we have all the
- <sup>22</sup> data on potential carcinogens and whether or not
- <sup>23</sup> they cause chronic inflammation for sure. I
- <sup>24</sup> think that, you know, we're still getting that
- <sup>25</sup> data.

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- Q. Have you ever diagnosed a patient with a talc-related ovarian cancer?
- <sup>3</sup> A. It's entirely possible that I have, but
- <sup>4</sup> I have not used polarized light microscopy on
- <sup>5</sup> ovarian tumors, so it's possible I have and
- 6 didn't look for talc -- didn't look for talc.
  - MR. KLATT: Objection. Nonresponsive.
  - Q. My question was: Have you ever
- <sup>9</sup> diagnosed a patient with a talc-related ovarian
- cancer, meaning you have said, "Your cancer is related to talc use"?
- A. Well, first of all, I wouldn't have said that if I'm not looking for talc.
  - But secondly, in our pathology reports, even though we're thinking and looking at causation,
  - 6 we're not necessarily putting in our individual
- <sup>17</sup> patient reports what caused their cancer.
  - We're certainly putting the diagnosis
- 19 together with their medical history and their --
- to kind of make all the pieces fit together, but we're not necessarily in every patient putting
- 22 out a report on what causes their cancer.
- MR. KLATT: Objection. Nonresponsive.
- MS. AHERN: Objection. Nonresponsive.
  - Q. I just want to know if you've ever

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- <sup>1</sup> actually diagnosed a patient with a talc-related
- <sup>2</sup> ovarian cancer. It sounds like the answer is no.
- If it is, it's okay. I need an answer.
- <sup>4</sup> A. I'm trying to answer your question.
- <sup>5</sup> Honestly, it's entirely possible that I have.
- But have I specifically put in a patient's
   report, "This ovarian cancer was caused by tale,"
- 8 no.9 (
  - Q. Thank you. That's all I was asking.
- What about at tumor boards? Do you attend tumor boards?
- <sup>12</sup> A. I do.
- Q. Have you ever suggested in a tumor
- board meeting with other colleagues that a
- particular patient's ovarian cancer was caused by talc use?
- A. I've certainly discussed with
- <sup>18</sup> oncologists and radiation oncologists about my
- 19 recent work. Again, it's been only in the last
- year and a half that I have really done this deep
- <sup>21</sup> dive in this literature.
- And I've certainly talked to radiation
- oncologists, oncologists about it at tumor boards
- <sup>24</sup> in a way of sort of educating them about my
- findings, but we haven't discussed in the context

Page 318 Page 320 <sup>1</sup> of a particular patient. <sup>1</sup> asbestos in it. Q. And were these discussions with Are you choosing to believe the plaintiffs' <sup>3</sup> radiation oncologists, were these people that asbestos experts over Ms. Pier's testimony? 4 focused on -- if they focus on -- gynecologic MR. TISI: Objection. <sup>5</sup> malignancies? Were they more pulmonary? Is A. Again, I think these were pieces of <sup>6</sup> there a difference with radiologists in terms of 6 information for me. I wasn't relying on her -the exhibit from her testimony for my general <sup>7</sup> specialty? A. There are some subspecialties. In this causation. I wasn't -- and I didn't see one, they were more general radiation Dr. Longo's reports until very late in my process oncologists. from what I recall. 11 Q. Okay. It's interesting information for me. It's 12 MS. AHERN: How much time do we have? 12 informative in that if the talcum powder products 13 THE VIDEOGRAPHER: Fifteen minutes. cause [sic] asbestos, that certainly lends 14 MS. AHERN: I'm going to turn it over significance to plausibility. But I'm --MR. ROTMAN: Do you want to reread your to my colleagues so they have an opportunity to ask questions. Thank you very much. I answer there? I think you misspoke. 17 appreciate it. THE WITNESS: Okay. Sorry. 18 THE WITNESS: Thank you. A. Yes. I did. If the talcum powder 19 MR. KLATT: How much time do we have? contains asbestos, that certainly adds to the We're at 6:37 right now. plausibility. But I'm not opining on whether or 20 21 Are you ready for me to continue? not talcum powder products contain asbestos. **CROSS-EXAMINATION** 22 Q. And you wouldn't have the expertise to 22 23 BY MR. KLATT: decide that Dr. Longo's testimony about asbestos Q. Dr. Kane, are you ready to continue? <sup>24</sup> in talc is more credible than Ms. Pier's 25 A. Yes. testimony about asbestos in talc, do you? Page 319 Page 321 Q. Can you hear me okay? A. I have a, I would say, cursory 1 <sup>2</sup> knowledge of how they would test for asbestos. I 2 A. Yes.

- Q. Yes. Dr. Kane, my name is Mike Klatt,
- 4 and I represent a company called Imerys Talc
- America in this case.
- Before this lawsuit, have you ever heard of
- 7 Imerys Talc America?
- 8 A. I don't believe I had, no.
- 9 Q. Do you know what Imerys Talc America 10 does?
- 11 A. From my understanding, they mine talc,
- 12 and they supply -- they're the talc -- one of the
- talc suppliers for Johnson & Johnson.
- Q. You said earlier you reviewed an <sup>15</sup> exhibit of Julie Pier's deposition.
- 16 Do you know who Julie Pier is?
- 17 A. I know she was a designated
- 18 representative. I don't know if it was for J&J
- or for Imerys off the top of my head.
- 20 Q. Ms. Pier works at Imerys, and she's an
- 21 expert microscopist and at analyzing talc for any
- 22 extraneous substances like asbestos.
- 23 She testified that the evidence you looked
- at did not indicate in any way that talc that
- ended up in Johnson & Johnson's baby powder had

- couldn't say that I am an expert in the methods
- that they use to detect asbestos.
- Q. But my specific question is: You don't
- 6 have the expertise to determine that Dr. Longo's
- testimony about asbestos and talc is more
- credible with or more believable or more
- scientifically valid or less scientifically valid
- than Ms. Pier's testimony about asbestos and
- 11 talc; correct?
- 12 That's my question.
- 13 A. Again, it's pieces of information for
  - me. I don't know anything, really, about
- <sup>15</sup> Dr. Longo versus Ms. Pier. I just have seen the
- exhibit from Ms. Pier's testimony and Dr. Longo's
- report, but I don't have more information nor
- have I really sought it out about their
- credentials. I was just using it as pieces of
- 20 information.
  - Q. But again my question is: You have no ability or expertise on your own to judge whether
- Ms. Pier's testimony that there's not asbestos in
- talc is correct or Dr. Longo's testimony is
- correct. That's not an area of your expertise;

1 correct?

- A. It -- I wouldn't say I'm an expert in
- 3 that area.
- Q. You mentioned earlier in response to
- <sup>5</sup> Ms. Ahern's questions, you talked about heavy
- Are you aware that IARC has not singled out
- 8 a single heavy metal as a cause of ovarian
- cancer?
- 10 A. Yes. I have seen that. I have
- 11 reviewed the IARC monograph on heavy metals, and
- 12 I'm aware.
- 13 But, again, it's another sort of piece of
- 14 the plausibility puzzle. If we -- we know that
- <sup>15</sup> some of them are either listed as carcinogens or
- <sup>16</sup> probable carcinogens. If they're in the talcum
- powder product, that's just another piece of the
- <sup>18</sup> biological plausibility puzzle. And I --
- 19 Q. Well, is it your -- I'm sorry. I
- 20 didn't mean to cut you off.
- 21 A. No. Sorry.
- 22 Q. Is it your testimony that if something
- 23 is considered a carcinogen for one organ system
- 24 by IARC, that it's capable of causing cancer in
- <sup>25</sup> all organ systems?

- Page 324 <sup>1</sup> at the end of the answer before you started your
- <sup>2</sup> next question.
- A. So I'm aware that they're in these
- 4 things. What I'm looking at is a product that's
- <sup>5</sup> used frequently and for -- in a lot of women for
- <sup>6</sup> a long duration of time. So their exposure -- if
- they are in the talcum powder, their exposure to
- those heavy metals would be greater than the
- exposure they're getting in the environment.
- Q. Those same, exact heavy metals are in
- drinking water, bottled water, food, and
- multivitamins that people take every single day,
- and there's no evidence that they cause ovarian
- cancer; correct?
- A. There has not been a link with heavy
- metals to ovarian cancer specifically as of yet.
- Q. And there's no evidence you're aware of
- that the tissue levels of any heavy metals are
- higher in talc users than in women who never used
- 20 talc: correct?
- 21 A. I don't -- I'm not aware of that study
- 22 being done.
- 23 Are you talking tissue levels?
  - Q. Blood levels --
- 25 A. Blood levels.

Q. -- tissue levels. Anything you want.

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<sup>2</sup> today, I think different tissues respond in You're -- there's no medical or scientific

24

- <sup>3</sup> evidence that you would tell this court that the
- 4 levels of heavy metals in women who use talcum
- <sup>5</sup> powder in the genital area are higher than women
- <sup>6</sup> who have never used talcum powder?
- A. I'm not aware of studies that have been
- done that have looked at the levels of those
- heavy metals in ovarian tissue or blood levels.
- Q. Earlier you mentioned there was a study
- about changing gene expression in the presence of
- talc in mesothelial cells?
- 13 A. Yes.
- Q. The mere fact that you have changing
- gene expression in no way implies something is
- carcinogenic; correct?
- 17 A. It -- it's evidence that it's changing 18
- gene expression within those cells, and --19 Q. If -- I'm sorry. Go ahead.
- 20 A. And the genes in that study that had
- increased expression are involved in the
- inflammatory -- are pieces in the inflammatory
- 23 response.
- Q. You're aware that many of those genes
- <sup>25</sup> in that study were antioxidant genes and

- Page 323
- A. As I've testified several times here
- <sup>3</sup> different ways to different carcinogens. So I
- 4 would not make a blanket statement that a
- <sup>5</sup> carcinogen in one site will definitely cause
- <sup>6</sup> cancer in another site.
- However, having carcinogens, known
- <sup>8</sup> carcinogens in a product, it can add to the
- <sup>9</sup> biological plausibility. And we're not talking
- 10 about these heavy metals sort of in the
- <sup>11</sup> environment. I mean, these are -- there's
- <sup>12</sup> evidence that they are in a product that's used
- <sup>13</sup> regularly and frequently.
- Q. Are you -- are you aware that the same, <sup>15</sup> exact heavy metals are in bottled drinking water?
- A. So, again, I don't know what the levels
- of these heavy metals are in drinking water. I <sup>18</sup> know that they are found in the environment
- 19 commonly.
- 20 Q. Are you aware they're in foods?
- A. I'm aware that they are in the <sup>22</sup> environment and foods regularly. Yes. But --
- 23 Q. Are you aware they're in multivitamins? 24 MR. ROTMAN: Wait. Wait.
- 25 I was hearing a "but" and not a period

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anti-inflammatory genes that were elevated;
 correct?

A. They can regulate or deregulate, and I think it's interesting -- let's say that they were antioxidant -- they were producing antioxidant enzymes. I think that is evidence that it's trying -- that the cell is trying to respond and is trying to prepare itself for an

9 insult, an inflammatory insult. Otherwise, why 10 would that gene be expressed?

So, I mean, there's increased and decreased regulation.

O But Dr Kane you're aware that

Q. But, Dr. Kane, you're aware that strenuous exercise can increase gene expression of prooxidants, antioxidants, proinflammatory, anti-inflammatory proteins; correct?

A. Strenuous exercise can increase
 antioxidants in proinflammatory,
 anti-inflammatory proteins.

But, again, I'm opining about a product that someone is going to be using regularly with frequency over a long period of time.

Q. You're aware that --

A. It just adds to the -- I'm not -- you know, I don't have an opinion about whether or

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not those heavy metals are in talc. I've looked
 at some evidence that they are there, but I don't

<sup>3</sup> have an opinion that they're actually in talc.

4 It's just another piece of evidence, again, for
5 the biological plausibility.

Q. Well, you're not saying that people who regularly engage in chronic exercise, chronic strenuous exercise, for a long period of time are

9 at increased risk of cancer because they have

increased gene expression, are you?
 A Well there hasn't been epide

A. Well, there hasn't been epidemiologic evidence that is consistent that people who do routine strenuous exercise get cancer.

Q. The Buz'Zard study you cited, that actually showed that talc -- increasing doses of talc decreased release of reactive oxygen species from ovarian cells, not increased it; correct?

A. I believe it was different -- I would have to look at the study, but it was over different time periods. It fluctuated.

Q. The highest level of reactive oxygen species in the Buz'Zard study was the group of cells that had no talc applied at all; correct?

A. I'd have to re-review the study.

Q. Let's --

24

25

Page 328 MR. KLATT: Can we mark that?

<sup>2</sup> MR. ROTMAN: Can we get a time check?

THE VIDEOGRAPHER: 6:30.

MR. ROTMAN: Thank you.

(Article entitled "Pycnogenol
 reduces Talc-induced Neoplastic

Transformation in Human Ovarian Cell

8 Cultures" marked Exhibit 26.)

MS. AHERN: That's 26.

Q. Referring to Exhibit 26, Dr. Kane, is this the Buz'Zard study you were mentioning earlier?

A. Yes, this is it.

Q. And if you'll flip over to Page 3 -
secuse me, 582, Figure 3, do you see Figure 3

is --

MR. ROTMAN: Can I have a copy of that, please?

MR. KLATT: I'm sorry?

MR. ROTMAN: I'm waiting for a copy of that.

MR. KLATT: Oh. Yes. We do provide copies.

MR. ROTMAN: This is Exhibit No. 1? THE WITNESS: I'm sorry. Which table?

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ked 1 MS. AHERN: Twenty-six.

24

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<sup>3</sup> Q. Figure 3. Page 582.

MR. ROTMAN: What exhibit are we on?

5 COURT REPORTER: Twenty-six.

6 MR. ROTMAN: Thank you.

<sup>7</sup> BY MR. KLATT:

<sup>2</sup> BY MR. KLATT:

Q. And you see Figure 3 is "ROS."

<sup>9</sup> That stands for reactive oxygen species?

<sup>10</sup> A. That's --

Q. And, by the way, ROS are generated by every cell of the body every day, 24 hours a day; correct?

every cell of the body every day, 24 hours a da correct?

A. Reactive -- you do see it in daily cell

life. But, again, I'm talking about an
 additional exposure, an agent that that is being
 analist in addition to what you're assist on

applied in addition to what you're seeing on -basically the cell has, as we just discussed,

they have ways of mitigating reactive oxygen

20 species.

The cell can increase their antioxidant enzymes, but at some point, they can get

overloaded. So if you're giving it a higher dose at a higher frequency than those systems can

<sup>25</sup> handle, you're going to have an increased risk of

- <sup>1</sup> mutagenesis.
- Q. Well, let's look at what Buz'Zard found
- when talc was applied to surface ovarian cells.
- Do you see that? That's Figure 3A up at the 5 top?
- 6 A. A, up at the top. Yes.
- Q. And you'll agree with me, you see on
- 8 the Y axis it says "Percentage of reactive oxygen
- species generation in OSE2a cells"; correct?
- 10 A. Yes.
- 11 Q. That's ovarian surface epithelial
- 12 cells: correct?
- 13 A. Yes.
- Q. And you'll see at the zero talc level 14
- 15 on the X axis --
- 16 A. Mm-hmm.
- Q. -- that had 100 percent talc -- excuse
- me -- a 100 percent reactive oxygen species
- generation at all three time periods; correct?
- 20 A. That is correct. And --
- 21 Q. And when talc was applied?
- 22 MR. ROTMAN: Wait. Wait.
- 23 Did you finish your answer?
- A. Well, we were just talking about how
- <sup>25</sup> cells can have innate ROS generation.

- <sup>1</sup> generation for each talc microgram.
  - Q. Do you see in the far right column,
  - <sup>3</sup> they applied 200 micrograms of hydrogen peroxide?

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- Q. And that resulted in a 200 percent
- <sup>6</sup> increase in reactive oxygen species during those
- time periods; correct?
- A. That is what it says. Yes.
- Q. And that's their positive control;
- 10 correct?
- 11 A. Let me just double-check.
- 12 If I'm remembering the study correctly, yes,
- you are -- you are right.
- Q. People gargle with hydrogen peroxide; 14
- 15 correct?
- 16 A. They shouldn't.
- 17 Q. Well, you know, it's allowed on the
- 18 bottle.
- 19 You know that; correct?
- 20 A. If you're telling me they gargle with
- 21 it, that's fine.
- 22 Q. Well, they put it on cuts; right?
- 23 A. They shouldn't put it on cuts. It's
- actually --
  - Q. It's sold for that, isn't it?

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- Q. And this graph shows that as you
- <sup>2</sup> applied increasing doses of talc, the level of
- <sup>3</sup> generation of reactive oxygen species in the
- <sup>4</sup> ovarian cells went down.
- It didn't go up; correct?
- A. Well, it goes up at -- what's the 50 --
- <sup>7</sup> the 50 micrograms per milliliter. It goes up at
- 8 that dose at the 120 hour, and then it goes up at
- <sup>9</sup> the 200 microgram level.
- 10 Q. That's not tale, is it?
- 11 A. I'm sorry. I'm looking at -- I'm
- 12 looking at -- it says "Talc micrograms per
- 13 milliliter," and then it lists the different
- 14 hours on the right; that they're color-coded to
- <sup>15</sup> the different hours.
- 16 Q. And 17 out of the 18 measurements they
- took when talc is applied to ovarian cells showed
- <sup>18</sup> the ovarian cells generated less reactive oxygen
- 19 species than no talc at all; correct?
- 20 A. And I --
- 21 Q. Is that correct?
- A. It looks like at different periods of 22
- 23 time at the 100 micrograms and 500, there was
- <sup>24</sup> less than the lower. But I'm not sure what the
- <sup>25</sup> threshold dose would be for optimal ROS

- A. I think most MDs would tell you that
- <sup>2</sup> it's probably better not to use hydrogen peroxide
- <sup>3</sup> on open cuts because it can cause a pretty severe
- <sup>4</sup> reaction.
- Q. You're aware that it's sold over the
- <sup>6</sup> counter in stores every day for -- as an
- antiseptic?
- A. Talcum powder is sold for everyday use
- on babies.
- 10 Q. So are you telling us that hydrogen
- peroxide now causes cancer?
- 12 A. I'm saying that it will release ROS
- species generation.
  - Q. Far more than talc; correct?
- 15 A. Based on this study, it appears that
- <sup>16</sup> way.

17

- Q. And you --
- 18 A. This one study. 19
  - Q. You agree with me this shows, as you
- apply talc, reactive oxygen species in ovarian
- cells decreases.
- 22 It doesn't increase at 17 out of 18 time
- 23 points; correct?
- 24 A. They're -- I will agree with you,
- <sup>25</sup> except there is a time point where it is

- <sup>1</sup> increased. And I don't know -- my caveat is I
- <sup>2</sup> don't know where the threshold would be where the
- <sup>3</sup> ROS would stop being generated.
- 4 Q. Is aspirin approved by any
- 5 pharmaceutical company or recommended by any
- 6 medical organization for prevention of ovarian
- <sup>7</sup> cancer?
- 8 A. That is not on the label description.
- <sup>9</sup> Q. If aspirin prevented ovarian cancer,
- don't you think it would be marketed for that
- $^{11}$  purpose?
- MR. TISI: Objection.
- MR. ROTMAN: Objection.
- A. I'm sure it may be after years of FDA
- 15 red tape and approval, but the literature --
- <sup>16</sup> again, I've said the literature is not as beefy
- <sup>17</sup> as the epi data when we're looking at aspirin and
- 18 NSAIDs.
- NSAID, in particular, is not as consistent.
- <sup>20</sup> The aspirin data does appear to be consistent in
- 21 lowering the risk, but there are not a lot of
- 22 studies looking at this yet.
- Again, though, just a piece of the puzzle
- <sup>24</sup> for a biologic plausibility.
- Q. Well, certainly, we're not at the point

A. I have to look at the studies. There

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- <sup>2</sup> might be one where it wasn't statistically
- <sup>3</sup> significant, but I think the majority of the ones
- <sup>4</sup> that looked at aspirin use showed a decreased
- <sup>5</sup> risk of ovarian cancer.
  - Q. Are you -- are you a member of the
- <sup>7</sup> International Society of Gynecologic
- 8 Pathologists?
  - A. I don't think I'm a member currently.
- <sup>10</sup> No.

9

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- Q. Have you ever been?
- <sup>12</sup> A. I believe so.
  - Q. It's not on your CV.
- <sup>14</sup> A. Okay. I'm not currently. I know that.
- Q. Are you a member of the American
- <sup>16</sup> Society of Clinical Pathology?
- <sup>17</sup> A. I actually am.
  - Q. It's not on your CV.
- A. Okay. That should be updated, then.
- Q. Have you ever been a member of any
- <sup>21</sup> working group or organization on the
- <sup>22</sup> classification of female reproductive organ
- <sup>23</sup> tumors?
  - A. No. I can't -- no.
  - Q. You mentioned the Surgeon General's

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- <sup>1</sup> for aspirin and ovarian cancer that we are, for
- <sup>2</sup> example, with aspirin in terms of cardiovascular
- <sup>3</sup> risk; correct?
- 4 A. I would agree with that sentiment.
- Q. And doctors and medical organizations
- 6 have recommended aspirin for reduction of
- <sup>7</sup> cardiovascular risk; correct?
- 8 A. That's correct. Although the dosage
- 9 has -- as of late, they're kind of parsing out
- 10 the -- they're reevaluating what dosages, but
- 11 you're correct.
- Q. And you can't cite a single medical
- 13 organization that at this point in time says the
- <sup>14</sup> evidence that aspirin reduces ovarian cancer is
- <sup>15</sup> sufficient that women should take it on a regular
- <sup>16</sup> basis to reduce ovarian cancer; correct?
- A. Well, I think I've said there aren't
- 18 that many studies yet. It's only -- that I'm
- <sup>19</sup> aware of, there are only a handful. They've been
- 20 consistent with aspirin. Not so much with NSAID.
- 21 That's, I think, as far as the evidence takes us
- 22 as this point.
- Q. There's actually studies showing that
- 24 chronic aspirin ingestion doesn't decrease
- ovarian cancer risk; correct?

- <sup>1</sup> report in 1964. You're aware that when that came
- <sup>2</sup> out about smoking, there were numerous studies in
- <sup>3</sup> the literature at that point in time showing that
- 4 the chemicals in cigarette smoke actually damaged
- <sup>5</sup> DNA and resulted in cancer; it wasn't based just
- 6 on epidemiology?
  - A. I think epidemiology -- my point was
- 8 that the epidemiology was the sort of first --
- <sup>9</sup> there were pathologists that had noticed on
- 10 autopsies in patients that smoked -- it was
- <sup>11</sup> actually pathologists and a surgeon in the early
- 12 years -- that had noticed some changes, some
- 13 squamous metaplastic changes.
  - But it was really the epi data that sort of
- <sup>15</sup> drove the research on smoking and tobacco
- <sup>16</sup> initially. But, again, there were some studies
- that had shown some pathologic changes in
- 18 smokers. That's true.
- Q. You're aware that the cohort studies,
- 20 the hospital-based case-control studies, and the
- population-based case-control studies all
- <sup>22</sup> uniformly showed that smoking increased the risk
- 23 of lung cancer; correct?
- A. That's correct.

25

Q. And that's not true for talc and

Page 338 Page 340 1 ovarian cancer: correct? <sup>1</sup> that one statement. A. Well, I have some issues with the Go ahead. 3 <sup>3</sup> cohort studies. MR. ROTMAN: If you want to do that, Q. I know that. that's fine. 5 But my statement is true; correct? BY MR. KLATT: A. But I think it's relevant because the Q. That draft -- Health Canada issued a <sup>7</sup> cohort studies, I don't believe, followed draft assessment that's undergoing a 60-day patients for a long enough time. public comment period; correct? 9 The Nurses' Health Study only asked about A. That's true. 10 talcum powder use once in 1982, so there's Q. And then they have up to two years to 11 certainly room for misclassifications of users as decide whether to take any action or no action at 12 never users. all: correct? 13 13 And some of -- some of -- again, there's A. Well, there's two pieces of that. From 14 smaller numbers because it's a -- it's a cohort 14 my understanding is that they've already done the <sup>15</sup> scientific. They've already done the literature 16 Q. You're aware that the National Cancer <sup>16</sup> review. They've already done their Bradford Hill 17 Institute doesn't agree with you on that, aren't <sup>17</sup> analysis, and they've come to the conclusion that they've come to. you? 19 19 A. I have seen the NCI website. I And then there's the public commentary. And <sup>20</sup> then there's the regulatory aspect of it. <sup>20</sup> certainly considered what they say about it. I 21 don't know if they have done the same type of Now, I am -- I would not claim to be an <sup>22</sup> analysis as I've done. I don't believe it's on <sup>22</sup> expert in regulatory. I know we have regulatory 23 their website what methodology they used and what experts that are coming on. But in -- from my <sup>24</sup> literature they reviewed. <sup>24</sup> understanding, the regulatory aspect is different So I'm aware of what they've stated. But, 25 than the scientific aspect. Page 339 Page 341 <sup>1</sup> you know, I've still done this extensive review MR. ROTMAN: Mike, you're done? I just <sup>2</sup> that I'm not sure they did to come to my 2 want to --3 <sup>3</sup> conclusion. MR. KLATT: I'm through. Q. You honestly don't know what the NCI MR. ROTMAN: I just want to go off the 4 <sup>5</sup> did in terms of review to come to their record. 6 conclusion, do you? We're done with seven hours. A. They didn't state what they did, so I MR. KLATT: Yes. I'm done. do not know. So that would -- but that's MR. TISI: Let's take a minute. <sup>9</sup> something that I'm thinking about when I'm taking THE VIDEOGRAPHER: Off the record, 10 into consideration. 10 6:31 p.m. 11 Q. And you are aware that they just 11 (A recess was taken.) 12 updated their statement that the evidence does 12 THE VIDEOGRAPHER: Back on the record, 13 not support a link between talc and ovarian 6:40 p.m. <sup>14</sup> cancer in January 2019, the same month we're **CROSS-EXAMINATION** 15 sitting here today? 15 BY MR. ROTMAN: 16 A. I don't know if I've gone to the NCI Q. Dr. Kane, I know it's been a long day <sup>17</sup> website this month. for you, but I'm going to ask you a few questions. I will be brief. But I'm also aware of Health Canada that 19 19 came out and did -- and we know what the A. Okay. 20 20 methodology and literature they -- they spelled Q. At one point today, you were asked some 21 it out very clearly what their methodology was, 21 questions by Attorney Ahern about certain 22 what literature review they did, and they came to 22 negative studies on inflammation, and she

MR. ROTMAN: Off the record, Mike?

MR. KLATT: Let me just follow up on

<sup>23</sup> the same conclusion that I did.

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mentioned Bonovast 2005 and Ni 2012, which she

24 asked you about.

Do you recall that?

25

A. Yes.

1

- 2 Q. She did not show you those studies, did 3 she?
- A. I don't believe I saw them.
- 5 O. Are you able to agree with her
- <sup>6</sup> characterization that these were negative studies
- without having -- without looking at them?
- A. I should have asked for them and had
- them in front of me while asking questions.
  - Q. Now, you were asked questions --
- 11 A. I mean answering questions.
- 12 O. -- throughout the day about
- 13 inflammation as a biologically plausible
- mechanism for explaining talc causing ovarian
- cancer in light of the epi study findings.
- 16 A. Yes.
- 17 Q. You were also asked questions about
- 18 cigarette smoking at various times throughout the
- 19 day?
- 20 A. Yes.
- 21 Q. Does cigarette smoking have an
- <sup>22</sup> inflammatory effect?
- 23 A. Yes.
- 24 O. What is the --
- 25 A. It does cause chronic inflammation.

- iust strike that.
  - You were asked questions about surgical

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- gloves and surgical-grade talc on surgical
- gloves.
- A. Yes.
- Q. Do you recall that?
- A. Yes.
- Q. And I think you were asked if you were
- aware of any studies linking the use of talcum
- powder on surgical gloves with the occurrence of
- ovarian cancer. 12
  - Do you recall that?
  - A. Yes.

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- 14 Q. Is there a difference, a notable
- difference, between talcum powder on surgical
- gloves and the talcum powder products in perineal
- use that, regardless of the constituent of the
- powder, that you would want to point out?
- 19 MR. KLATT: Objection. Form.
- 20 MS. AHERN: Same.
  - A. So a patient's exposure to surgical
- gloves are going to be infrequent and not of long
- duration. It's not the same type of exposure as
- <sup>24</sup> regular and frequent application of perineal
- 25 talcum powder that we're seeing in the epi data.
- Page 343
- Q. You were also asked questions about
- <sup>2</sup> heavy metals being present in food and water and
- <sup>3</sup> vitamins; correct?
- A. I remember. Yeah.
- Q. Do -- what is different between those
- <sup>6</sup> circumstances and the situation that we have been
- discussing all day today involving talcum powder?
- A. With talcum powder, we do have the epi
- <sup>9</sup> data that are consistent and show an increased
- 10 risk of ovarian cancer with talcum powder use.
- 11 Q. And with respect -- you were asked some 12 questions in relation to the Buz'Zard study about
- 13 hydrogen peroxide and the reactive oxygen species
- 14 reaction?
- 15 A. Yes.
- Q. Are you aware of any evidence that
- hydrogen peroxide -- the effect of hydrogen
- peroxide in the female genital tract?
- 19 A. I'm not aware that women routinely use
- <sup>20</sup> hydrogen peroxide in the female genital tract.
- Q. And is there anything in particular
- 22 about the -- that part of the anatomy that where
- <sup>23</sup> certain agents, exposure to certain agents, would
- <sup>24</sup> raise any particular concerns -- strike that.
- 25 I think that was a bad question, so I'll

- MR. ROTMAN: No further questions.
- <sup>2</sup> It's 6: --
- (Discussion off the record.)
- MR. ROTMAN: You're right.
- BY MR. ROTMAN:
- O. I have some questions for you about
- your testimony on the Harlow paper.
  - A. Okay.
- 9 Q. Can you pull that out in front of you,
- 10 which was Exhibit 20?
  - A. Okay.
- 12 Q. Can you turn to Table 3.
  - A. Okav.
  - Q. And do you recall that you were asked
- questions about dose-response in this study?
  - A. Yes.
- 17 Q. And do you recall that you were
- specifically asked questions about this Table 3? 19
  - A. Yes.
- Q. Could you look at the middle part of
- <sup>21</sup> Table 3, at the column with "adjusted odds 22 ratios"?
- 23 A. Yes.
- 24 Q. What can -- what do you observe with
- <sup>25</sup> respect to the adjusted odds ratio as the -- as

- <sup>1</sup> the -- as the number of applications goes from <sup>2</sup> less than 1,000 to greater than 10,000?
- A. The adjusted ORs go from -- the null, 4 1.0 at none, 1.4 at less than 1,000, to 1.7 at

greater than 10,000.

- Q. And so what, just looking at the adjusted odds ratio, what --
  - A. It's an increase with increased --
- 9 Q. -- what is your takeaway?
- 10 A. So it does show an increased odds ratio <sup>11</sup> with increased applications.
- 12 The confidence intervals do include the null, but they're -- the higher end, it's higher confidence interval at the upper end.
- 15 And it's not very far from the null on the 16 lower end.
- 17 And it, in fact, includes -- it's 1.0 at 18 greater than 10,000.
- 19 Q. And so for the 1,000 to 10,000 <sup>20</sup> applications, the lower bound of the confidence 21 interval is .9?
- 22 A. Correct.
- 23 Q. And how close is that to being a
- statistically significant finding?
- 25 A. Very close.

A. Yes.

- O. And this is -- this is in the
- <sup>3</sup> "Discussion" section of the paper; is that right?

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- Q. And do you see in the paragraph that
- <sup>6</sup> I'm pointing to that begins with "Our study"?
  - A. Yes.
- Q. Could you read into the record and
- comment on the last sentence in that paragraph.
- A. "Daily versus less-than-daily talc use and talc use for more than ten years versus less 12 than ten years were associated with greater risk
- for ovarian cancer."
  - Q. And can you comment on that?
- 15 A. So that does show a trend for a dose-response.
- 17 MR. ROTMAN: Okay. So I have 6:48.
- 18 You've got eight minutes.
  - **RECROSS-EXAMINATION**
- BY MR. KLATT:
- Q. That Harlow study you were just looking
- <sup>22</sup> at --

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- 23 A. Yeah.
  - Q. -- is that the 1992 Harlow study?
- 25 A. It's the 1992 from Exhibit 20.

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- Q. And can you also take a look at the
- <sup>2</sup> discussion on that page in the left-hand column
- <sup>3</sup> in the paragraph that begins with "We also
- 4 examined"?
- 5 A. Okay.
- Q. Is there a discussion in that paragraph
- <sup>7</sup> concerning the author's discussion of
- dose-response?
- 9 A. Yeah. There's a sentence that states,
- 10 "The categorical analysis showed that relative to
- 11 nonusers, the risk was greatest in women who
- 12 applied talc at least once per day. When years
- 13 of use was included as a continuous variable, the
- 14 test for linear trend was 3.32, p-value of .07.
- 15 "The categorial analysis show that relative 16 to nonusers, women who applied talc for more than
- 17 ten years were at a 60 percent greater risk for
- <sup>18</sup> ovarian cancer. Likewise, perineal applications
- 19 of talc early in life, before age 20, or
- <sup>20</sup> applications within six months of diagnosis
- 21 reference age for controls produced the stronger
- 22 ORs."
- Q. And I'd like to also call your
- 24 attention to the page 24 in the right-hand
- 25 column.

- Q. And can you look on the last page of
- <sup>2</sup> this study, the page where the article ends and
- the reference begins.
- Did Harlow find the strength of association
- between genital use of talc and ovarian cancer
- was strong or weak?
- A. So they use -- they say, "Because the
- overall association between genital use of talc
- and ovarian cancer remains weak."
- And, again, "weak" is sort of a relative.
- 11 I've seen weak to moderate with this odds ratio.
- <sup>12</sup> And this is also 1992.
  - MR. KLATT: Object. Nonresponsive.
  - Q. I'm simply asking you, Dr. Kane, does
- <sup>15</sup> Harlow say strength of association between
- ovarian cancer and talc use is strong or weak? 17
  - A. Well, I'm putting it in context. He
- states -- I agree with you that's what the words
- say, but I'm putting it in context in that "weak
- to moderate" is used amongst epidemiologists for
- this level of overall risk.
  - And this is 1992, so there wasn't the
- subsequent studies that have gone on that show
- consistent, similar overall risk odds ratio.
  - O. And would it be correct that the

- Page 352 <sup>1</sup> statement that I asked you to read says in full,
- <sup>2</sup> "Because the overall association between genital <sup>2</sup> but the authors are aware. Many of them talk
- <sup>3</sup> use of talc and ovarian cancer remains weak, it
- 4 is unlikely that this exposure disease pathway is
- <sup>5</sup> the principal one involved in ovarian cancer 6 etiology"?
  - Is that what Harlow said?
- A. That's what it states. But, again,
- <sup>9</sup> that is 1992. This is the very beginning of the epi data looking at this exposure and ovarian

<sup>11</sup> cancer.

- 12 MR. KLATT: Object and move to strike everything after "That's what it says."
- 14 Q. And, by the way, the odds ratio that <sup>15</sup> Harlow found overall was 1.5.
- 16 And that's even a little higher than the odds ratios the more recent meta-analyses have shown: correct?
- 19 A. So --
- 20 Q. So they're even weaker than Harlow.
- 21 A. I'm sure some epidemiologists might
- 22 take -- I'm not -- but, again, I've seen, even
- <sup>23</sup> with 1.3 and 1.4, epidemiologists refer to that 24 as "moderate."
- 25 So I don't know if it's semantics, but it's

- <sup>1</sup> element of recall bias in case-control studies,
- <sup>3</sup> about that and discuss why they feel recall bias
- 4 wasn't an explanation.
- And, again, we're talking about multiple
- 6 studies over numerous populations over different
- periods of time, most of them well before the
- general public knew about an association between
- talcum powder and ovarian cancer.
- And even further, the fact that there's a strong association in the literature with serous
- 12 invasive cancer would argue against a recall bias
- because the lay public is not knowledgeable about
- the histologic subtypes of epithelial ovarian
- carcinoma.
- 16 Q. Let me ask you this, Dr. Kane: We 17 lawyers, before we have to go to trial, like to
- know if the prospective jurors have already made
- up their mind about the case.
- 20 Do you know if in any of these case-control studies where the women who had ovarian cancer,
- <sup>22</sup> were they asked before they entered the study,
- 23 "Do you have a preconceived notion about what
- caused your ovarian cancer?"
  - A. I'm not aware of a case-control design

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- <sup>1</sup> 1.3. It's a 30 percent increased risk. In this
- <sup>2</sup> case, 1.5, a 50 percent increase in risk. And in
- <sup>3</sup> a rare disease like ovarian cancer, that's
- 4 significant.

17

- 5 Q. And Harlow calls a 1.5 odds ratio weak; 6 correct?
- A. That's what he says in this 1992 paper.
- O. And you'd agree with me the more recent
- 9 meta-analyses of talc and ovarian cancer have a 10 lower odds ratio than 1.5?
- 11 A. They seem to be between 1.3 and 1.4, but the important thing to me is the consistency.
- O. And you're aware that epidemiologists 14 say with case-control studies that odds ratios in 15 the range of 1.0 to 1.5 are well within the range <sup>16</sup> that can be explained by bias and confounding?

MR. ROTMAN: Objection.

- 18 A. I think all of the studies were
- 19 aware -- all of the authors were aware of potential recall bias and confounding and sought
- 21 to control as much as possible those factors in
- 22 their control studies. Most of them, I feel,
- <sup>23</sup> were relatively well-designed to assess for and <sup>24</sup> adjust for multiple confounding factors.
- 25 And as far as recall bias, there's an

- 1 that would ask that question because even asking
- 2 that question would potentially add an element of
- 3 recall bias --
  - Q. But if a woman already --
    - MR. TISI: She wasn't finished.
  - Q. Were you finished?
- A. I was going to say in a lot of these
- studies, they also asked about smoking history
- <sup>9</sup> and other potential lifestyle issues in addition
- 10 to talcum powder use that would -- and yet, those
- 11 types of questions didn't show an elevated risk
- 12 like talcum powder products.
- Q. Well, wouldn't you want to know --
- 14 before you interviewed the women who have ovarian
- 15 cancer, wouldn't you want to know if they have a
- 16 preconceived notion about what caused their 17 ovarian cancer so if you didn't exclude them from
- 18 the study, at least you could take that
- 19 preconceived bias into account when you did the
- 20 statistics?
- A. I would think if you're designing a
- 22 case-control study and trying to avoid recall
- 23 bias, there are better ways to do that because
- <sup>24</sup> just by asking, "Do you have a preconceived
- 25 notion about it?", you're introducing potential

	Page 354		Page 356
1	bias because they might think, Oh, maybe there is	1	Yes. It involves an inflammatory state.
	an association. And you're adding bias,	2	MR. KLATT: Thank you, Doctor.
3		3	MR. TISI: Just one question.
4	Q. You mentioned cigarette smoking just a	4	(Discussion off the record.)
	minute ago in response to Mr. Rotman's questions.	5	MR. ROTMAN: We're done.
6	And you said cigarette smoking involves a	6	MR. TISI: Thank you.
7		7	THE VIDEOGRAPHER: Here ends today's
8	correct?	8	•
9		9	deposition. Off the record, 6:58 p.m.
	A. There is an inflammatory response in	10	(Deposition concluded at 6:58 p.m.)
10	<del>-</del>		
11	Q. But cigarette smoking has not been	11	
12		12	
13	forms of ovarian cancer, which is serous invasive	13	
14	and endometrioid invasive; correct?	14	
15	A. So, again, different tissues will	15	
16	P	16	
17	Mucinous carcinoma has been associated in some	17	
18	studies with smoking, so there is evidence that	18	
19	epithelial ovarian cancer can be caused by	19	
20	smoking.	20	
21	MR. KLATT: Object. Nonresponsive.	21	
22	Q. The two most common forms of invasive	22	
23	ovarian cancer serous, which is the most	23	
24	common, and endometrioid, which is the second	24	
25	most common have not been shown to be elevated	25	
	Page 355		Page 357
1	_	1	1 age 337
2	as a result of smoking; correct?	-	ERRATA
3	A. The data has not shown an association	2	EKKATA
4	our con these two types with smeaning.	3	PAGE LINE CHANGE
_	Q. Even though smoking involves a chronic	4	THOE EINE CHANGE
5	minute of state, contest.	5	REASON:
7	A. But, again	6	
8	Q. That is did you hear my question?	7	REASON:
	Even though smoking involves a chronic	8	
9	inflammatory state; correct?	9	REASON:
10	A. We're talking about different types of	10	
11 12	exposures.	11	REASON:
13	Q. Does smoking	12	
14	A. Different agent	13	REASON:
15	MR. ROTMAN: One second, Mike.	14	
	Do you want an answer to the question?	15	REASON:
16	Because you're cutting	16	
17	DI WIK. IKE/III.	17	REASON:
18	Q. My question is: Does smoking	18	
19	involve	19	REASON:
20	MR. ROTMAN: Wait. Wait, Mike. Let	20	
21	her answer the question, and then you're done	21	REASON:
22	because were over.	22	
23	Do you know what the question was?	23	REASON:
24	A. Does smoking involve an inflammatory	24	
25	state?	25	REASON:

	Page 358	
1	ACKNOWLEDGMENT OF DEPONENT	
2	ACKINO W LEDUWENT OF DEPONENT	
1	I. do	
3	I,, do hereby certify that I have read the	
	foregoing pages, and that the same	
4	is a correct transcription of the answers	
5	given by me to the questions therein	
	propounded, except for the corrections or changes in form or substance, if any,	
6	noted in the attached Errata Sheet.	
7	noted in the attached Errata Sheet.	
8	SARAH E. KANE, M.D. DATE	
9		
11		
12		
13		
14		
1 -	Subscribed and sworn	
15	to before me this, 20	
16	day of, 20	
	My commission expires:	
17	F	
18	N. D.I.	
19	Notary Public	
20		
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	Page 359	
1	Page 359 CERTIFICATE	
1 2		
	CERTIFICATE	
2	CERTIFICATE COMMONWEALTH OF MASSACHUSETTS	
2	CERTIFICATE COMMONWEALTH OF MASSACHUSETTS SUFFOLK, SS.	
2 3 4	CERTIFICATE COMMONWEALTH OF MASSACHUSETTS SUFFOLK, SS. I, Janet M. Sambataro, a Registered Merit	
2 3 4 5	CERTIFICATE COMMONWEALTH OF MASSACHUSETTS SUFFOLK, SS. I, Janet M. Sambataro, a Registered Merit Reporter and a Notary Public within and for the Commonwealth of Massachusetts do hereby certify:	
2 3 4 5 6	CERTIFICATE COMMONWEALTH OF MASSACHUSETTS SUFFOLK, SS.  I, Janet M. Sambataro, a Registered Merit Reporter and a Notary Public within and for the Commonwealth of Massachusetts do hereby certify: THAT SARAH E. KANE, M.D., the witness whose	
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# Exhibit 140

# WEILL CORNELL MEDICAL COLLEGE CURRICULUM VITAE FORM

(REQUIRED FORMAT)

Signature (required):	Karla V. Ballman
Version date:	5 June 2018

### A. **GENERAL INFORMATION**

**Required Information:** 

Name: First, Middle,	Karla V. Ballman			
Last	Italia V. Dalillali			
Office address:	Healthcare Policy and Research LA-225 Weill Cornell Medical College 402 East 67 <sup>th</sup> Street New York, NY 10065			
Office telephone:	646-962-8023			
Office fax:	646-962-0281			
Home address:	430 East 63 <sup>rd</sup> Street Apt. 12G New York, NY 10065			
Home telephone:	507-301-3013	- (in-		-
Cell phone:	507-301-3013		-	
Beeper:	N/A			
Work Email: Personal Email:	kab2053@med.comell.edu kvballman@gmail.com			<u> </u>
Citizenship:	USA			
If not a U.S. Citizen, do you have:	Immigrant visa (green card)?  Non-immigrant Visa? Type:			

Optional Information (not required but helpful):

11/14/1960	
St. Cloud, MN	
	ARICO TO THE PERSON OF THE PER

Divorced
Caucasian

#### **B. EDUCATIONAL BACKGROUND**

1. <u>Academic Degree(s):</u> B.A. and higher; institution name and location; dates attended; date of award. Expand the table as needed.

Degree (abbreviation)	Institution Name and Location	Dates attended	Year Awarded	
B.A.	Macalester College St. Paul, MN	9/1979 to 5/1983	1983	
Scientiæ Magister (S.M.)	Massachusetts Institute of Technology Cambridge, MA	9/1985 to 6/1991	1989	
Ph.D.	Massachusetts Institute of Technology Cambridge, MA	9/1985 to 6/1991	1991	

 Post-doctoral training (include residency/fellowships): In chronological order beginning with postdoctoral training positions; include full titles, ranks and inclusive dates held. Expand the tables as needed.

N/A

3. Continuing Medical Education Courses/Certificates
N/A

4. Other Educational Experiences

N/A

#### C. LICENSURE, BOARD CERTIFICATION, MALPRACTICE

 <u>Licensure:</u> Every physician appointed to the Hospital staff, except interns, and aliens in the US via non-immigrant visas, must have a New York State license or a temporary certificate in lieu of the license.

N/A

2. Board Certification

N/A

3. Malpractice Insurance

N/A

# D. PROFESSIONAL POSITIONS AND EMPLOYMENT

# 1. Academic positions (teaching and research)

Title	Institution name and location	Dates held
Assistant Professor of Mathematics and Computer Science	Macalester College St. Paul, MN	8/1991 to 6/1999
Lecturer of Statistics	University of Auckland Auckland, New Zealand	1/1994 to 7/1996
Assistant Professor of Biostatistics	Mayo Clinic College of Medicine Rochester, MN	12/1999 to 7/2001
Associate Professor of Biostatistics	Mayo Clinic College of Medicine Rochester, MN	7/2001 to 10/2007
Adjunct Associate Professor of Biostatistics	University of Minnesota Minneapolis, MN	9/2007 to 7/2015
Adjunct Associate Professor	Biomedical Informatics and Computation Biology, University of Minnesota Rochester Rochester, MN	9/2010 to 7/2015
Professor of Biostatistics	Mayo Clinic College of Medicine	11/2014 to 7/2015
Professor of Healthcare Policy and Research Tenure awarded (11/2016)	Weill Cornell Medical College New York, NY	7/2015 to present

# 2. <u>Hospital positions (e.g., attending physician)</u> **N/A**

# 3. Other Employment

Title	Institution name and location	Dates held
Actuarial Trainee	Minnesota Mutual Life Insurance Company St. Paul, MN	1983 to 1985
Consultant	AT&T Bell Labs Software Production Research Naperville, IL	1991 to 1994
Research Associate	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	1999 to 2002
Senior Research Associate	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2002 to 2004
Senior Associate Consultant	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2004 to 2007

Senior Associate Consultant	Division of Biomedical Informatics Department of Health Sciences Research, Mayo Clinic Rochester, MN	2005 to 2007
Group Statistician	American College of Surgeons Oncology Group (ACOSOG) Statistics and Data Center Rochester, MN	2006 to 2014
Chair	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2006 to 2008
Consultant	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2007 to 2008
Consultant	Division of Biomedical Statistics and Informatics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2008 to 2015
Associate Editor	Journal of Clinical Oncology	2010 to 2017
Deputy Editor	Journal of Clinical Oncology	2017 to present
Consultant	Department of Surgery, Mayo Clinic Rochester, MN	2012 to 2015
Director of Biostatistics	Alliance Statistics and Data Center Rochester, MN	2013 to 2015
Division Chief of Biostatistics and Epidemiology	Healthcare Research and Policy Weill Cornell Medical College New York, NY	07/2015 to present

# E. EMPLOYMENT STATUS (current or anticipated)

Name of Employer(s): Weill Cornell Medical College	
Employment Status (choose one, delete the others): Full-time salaried by Weili Cornell	

# F. <u>INSTITUTIONAL/HOSPITAL AFFILIATION</u> N/A

### G. PERCENT EFFORT AND INSTITUTIONAL RESPONSIBILITIES

WCMC ANTICIPATED % EFFORT	(%)	Does the activity involve WCMC students/researchers? (Yes/No)
TEACHING	20%	yes
CLINICAL	0%	
ADMINISTRATIVE	40%	no
RESEARCH	40%	yes
TOTAL	100%	

#### **INSTITUTIONAL RESPONSIBILITIES**

Teaching (e.g., specific teaching functions, courses taught, dates: For guidance refer to Teaching
 <u>Metrics</u> table. Report your teaching activities in the 4 areas of teaching shown below. To provide a
 more detailed teaching report, use the <u>Teaching Activities Report</u> template or <u>Educator Portfolio</u>
 template (strongly encouraged). Refer to it here as an attachment (e.g., see attached), and attach it
 to the CV.

<u>Didactic teaching:</u> (e.g., lectures, continuing medical education courses, grand roun development programs, seminars, tutorials)	ds, professional
Protocol Development (tutorial leader, Mayo Clinic College of Medicine) Health Sciences Grand Rounds	Dates 2008-2012
Mentorship: (e.g., mentor for medical student, graduate student, resident, clinical or research fellow or junior faculty projects; service as graduate student thesis advisor member)	
8 M.S. candidates in the Clinical Research Master's degree program (Mayo Clinic College of Medicine)  Served on five M.S. thesis committees for M.S. candidates in the Clinical Research Master's degree program (Mayo Clinic College of Medicine)  Thesis advisor to 4 students in the Biomedical Informatics and Computational Biology M.S. degree program	Dates 2004-2015 2004-2015 2012-2015
Clinical teaching: (e.g., teaching in the clinic or hospital including bedside teaching, operating room, preceptor in clinic)	teaching in the
,	Dates
Administrative teaching leadership role: (e.g., residency or fellowship director, course or seminar director or co-director)	
Probability and Mathematical Statistics (course director, Macalester College) Introductory Statistics (course director, Macalester College) Mathematical Modeling (course director, Macalester College) Calculus II (course director, Macalester College) Calculus III (course director, Macalester College) Applied Probability (course director, Macalester College) Data Analysis and Statistics	Dates 1991 1991, 1992 1991, 1992 1992 1992 1992, 1993, 1996, 1998

Mathematical Statistics	1993, 1994, 1996, 1997,
Stochastic Methods in Management Science (course director, University of Auckland)	1998
Decision Analysis (course director, University of Auckland)	1993, 1997, 1999
Data Analysis with R (course director, University of Auckland)	1994, 1995
Statistics Minor Curriculum Development (Macalester College)	1994
Elementary Statistics (course director, Macalester College)	1994, 1995
	1995-1996
Linear Algebra (course director, Macalester College)	1996, 1997, 1998
Senior Capstone (course director, Macalester Coflege)	1996
Applied Multivariate Statistics (course director, Macalester College)	1997, 1998
Differential Equations (course director, Macalester College)	1998
Experimental Design and Data analysis (course director, Macalester College)	1998
Introductory Statistical Method I (course director, Mayo Clinic College of Medicine)	1998
Special Topics in Health Sciences Research (course director, Mayo Clinic College of	1999
Medicine)	2000-2003
Introductory Statistics Methods II (course director, Mayo Clinic College of Medicine)	2002, 2005
Clinical Trials (course director, Mayo Clinic College of Medicine)	2003-2004
Introduction to Biostatistics (course director, Executive MBA/MS program, Weill Cornell	2010, 2011
Medicine)	2017-Present

- Clinical care (duties, dates: To document clinical activities use the table below or, to document
  extensive clinical activities use the <u>Clinical Portfolio template</u> (strongly encouraged). Refer to it here
  as an attachment and attach it to the CV.
   N/A
- 3. <u>Research (duties, dates):</u> Summarize research activities in the table below. Provide key contributions, and annotate key grants and publications or use a <u>Statement of Key Contributions</u>. Refer to it here and attach it to the CV.

Research Activity / Key Contributions Dates	
See Statement of Key Contributions	

4. <u>Administrative Activities (duties, dates):</u> Describe administrative activities in the table below. To document administrative activities more extensively use a supplemental statement, refer to it here and attach it to the CV.

Administrative Activity	Date
Education Committee Member (Health Sciences Research, Mayo Clinic)	2000 to 2002
Education Committee Chair (Health Sciences Research, Mayo Clinic)	2002 to 2007
Education Committee Member (Clinical Research Training Program, Mayo Clinic)	2001 to 2006
Executive Committee Member (Clinical Research Training Program, Mayo Clinic)	2001 to 2005
Master's Examination Committee Member (Clinical Research Training Program, Mayo Clinic)	2002 to 2015
Curriculum Committee Chair (Clinical Research Training Program, Mayo Clinic)	2002 to 2006
Data Safety and Monitoring Board Member (Mayo Clinic Cancer Center)	2003 to 2006
Clinical Studies Oversight Committee Member (Mayo Clinic Cancer Center)	2003 to 2006
Neuro-Oncology Executive Committee Member (Mayo Clinic Cancer Center)	2003 to 2010
Neuro-Oncology Protocol Planning Committee Member (Mayo Clinic Cancer Center)	2003 to 2007
Education Committee Member (Mayo Graduate School)	2004 to 2006
Executive Committee Member (Department of Health Sciences Research, Mayo Clinic)	2004 to 2008
Education Programs Curriculum Committee Member (Center for Translational Activities,	2006 to 2008
Mayo Clinic)	
Division Chair (Division of Biostatistics, Health Sciences Research, Mayo Clinic)	2006 to 2008
Peer Review Research Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015
Research Executive Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015

Research Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015
Data Safety and Monitoring Board Member (Department of Surgery, Mayo Clinic)	2012 to 2015
Division Chief for Healthcare Policy & Research	2015 to present
Healthcare Policy & Research Promotions Committee Member	2015 to present
Weill Cornell Medicine Data Safety and Monitoring Board (alternative) Co-Chair	2017 to present

#### H. RESEARCH SUPPORT

#### **Summarize Past Research Support:**

- The Mayo Clinic Research Training Program funded by National Center for Research Resources (K30 RR 22296) from 06/1999 to 09/206; role: Associate Director
- Risk Factors for Venous Thromboembolism in the Community funded by NHLBI (R01 HL 66216) from 04/2001 to 04/2005; role: Co-investigator
- Angiotensin-II Blockade in Mitral Regurgitation funded by NHLBI (R01 HL 64928) fron 04/2001 to 03/2005; role: Co-investigator
- Core 1: Statistical and Administrative Core in: Gene Therapy for Vaso-occlusive disease funded by NHLBI (P01 HL 66958) from 09/2001 to 08/2008; role: Co-investigator
- Core B: Study Design and Analysis Core in: Molecular Markers of Glioma Initiation & Progression funded by NCI (P01 CA 85799) from 06/2001 to 05/2006; role: Principal Investigator
- GSK-3 and Associated Pathways in PNET funded by NINDS (R01 NS 40794) from 07/2002 to 11/2005; role: Collaborator
- Mitochondria and surgical myopreservation in aging funded by NIA (R01 AG 21201) from 09/2002 to 08/2008; role: Consultant
- Heart Failure in the Community funded by NHLBI ((R01 HL 72435) from 01/2003 to 06/2007; role: Coinvestigator
- Flavopiridol as a Potential Therapy in Multiple Myeloma funded by NCI (R01 CA 98118) funded from 07/2003 to 06/2008; role: Co-investigator
- MAGE-A3/HPV 16 Peptide Vaccines for Head and Neck Cancer funded by the NIDCR (R01 DE 15324) from 04/2004 to 12/2004; role: Co-investigator
- Xenograft Model for Studying Amplified EGFR in GBM funded by NCI (R01 NS 49720) from 08/2004 to 05/2006; role: Co-investigator
- Brain Tumor SPORE Core B Biostatistics funded by NCI (P50CA 108961) from 09/2004 to 08/2014;
   role: Core Director
- Global Differential Expression Profiling During Sudden Tumor Progression Using the Tumor Dedifferentiation Phenomenon as a Model funded by Mayo Clinic Foundation (CR20) from 04/2006 to 06/2010; role: Co-investigator
- Measles Virotherapy for Glioblastoma Multiforme funded by NCI (R21 CA 123839) from 08/2006 to 07/2010; role: Co-investigator
- 15. Utility of Serum and Tissue Biomarkers for Predicting Response to Androgen Deprivation Therapy in the Population of Men with Rising PSA Following Definitive Treatment in: SPORE in Prostate Cancer funded by NCI (P50 CA 91956) from 09/2006 to 08/2013; role: Co-investigator
- SPORE in Prostate Cancer—Biostatistics Core funded by NCI (P50 CA 91956) from 09/2006 to 08/2013;
   role: Core Director
- Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) funded by NCI (U10 CA 76001) with subcontract to Mayo from 03/2006 to 11/2014; role: Principal Investigator
- Epigenetic regulation of temozolomide responsiveness in glioblastoma funded by NCI (R01 CA 127716) from 01/2008 to 12/2012; role: Co-Investigator
- Correlative Science and Imaging Analysis for Z1031 funded by Breast Cancer Research Foundation (WU-09-200) with subcontract to Mayo fro m10/2008 to 09/2009; role: Principal Investigator
- A phase III randomized Double Blind study of Adjuvant ST1571 (Gleevee) versus Placebo in patients following the Resection of primary gastrointestinal Stromal Tumor (GIST) funded by Novartis from 12/2008 to 06/2009; role: Principal Investigator
- Mayo Comprehensive Cancer Center Grant funded by NCI (P30CA 15083) from 03/2009 to 07/2015; role: Statistician
- Novel Biomarkers for Aromatase Inhibitor Therapy funded by NCI (R01 CA 95614) from 04/2009 to 12/2011; role: Principal Investigator

- Optimizing Measles Virotherapy in the Treatment of Gliomas funded by NCI (R01CA 140620) from 07/2009 to 03/2011; role: Co-investigator
- ACOSOG Community Clinical Oncology Program (CCOP) Research Base funded by NCI (U10CA 149950) from 06/2010 to 07/2014; role: Co-investigator
- 25. Treatment patterns of patients with newly diagnosed malignant primary brain tumors funded by Monteris Medical from 09/2010 to 08/2011; role: Principal Investigator
- Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) in: Industry Supplement of Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) funded by Duke Clinical Research Institute from 12/2010 to 11/2011; role: Principal Investigator
- N1037 P95HER2 expression in metastatic breast cancer patients treated with trastuzumab on N0337 and NCCTG 98-32-52 funded by BioTheranostics/BioMerieux from 10/2011 to 3/2012; role: Co-investigator
- Part 1 N9831F-NCCTG-ICSC Validation study of Quantitative Single Gene Assessment of HER2 mRNA by qRT-PCR and Development and Testing of New HER2 Multi-Gene Signature funded by Genomic Health, Inc. from 04/2012 to 05/2015; role: co-Principal Investigator
- Therapeutic Strategy to Slow Progression of Calcific Aortic Valve Stenosis funded by National Center for Advancing Translational Sciences (UH2TR 000954) fro 06/2013 to 07/2015; role: Co-investigator
- Patient Centered: Risk Stratified Surveillance After Curative Research of Colorectal Cancer funded by a subcontract from a PCORI grant (CE-1304-6855) from 03/2014 to 07/2015; role: Principal Investigator
- Post-Treatment Surveillance in Breast Cancer: Bringing CER to the Alliance funded by a subcontract from a PCORI grant (CE-1304-6543) from 03/2014 to 07/2015; role: Principal Investigator
- 32. Statistics and Data Center for the Alliance for Clinical Trials in Oncology funded by NCI (U10CA 180882) from 04/2014 to 07/2015; role: Co-investigator
- Alliance NCORP Research Base funded by NCI (UG1CA 189823) from 08/2014 to 07/2015; role: Coinvestigator
- Improving How We Predict Toxicity for Older Women with Breast Cancer funded by Susan G. Komen Breast Cancer Foundation from 10/2014 to 09/2017; role: Principal Investigator (subsite)
- 35. Sarcoma Foundation from 11/2015 to 05/2017; role: Principal Investigator
- Clinical and Translational Science Center (2UL1 TR000457) funded by NIH from 06/01/12 to 05/31/17;
   role: Co-Investigator

#### For Current extramural and intramural research funding, provide the following for each award:

- 1. Source, amount, and duration of support (dates)
- 2. Name of Principal Investigator
- 3. Individual's role in project, including percentage (%) effort

#### **Current Research Support** (duplicate table as needed):

Source	NCI (U01CA 157715) subcontract SPECs Grant	
Amount	\$85,700 (subcontract amount of the larger grant)	
Duration	07/2012 to 06/2018	
Principal Investigator	Fred Hirsch	
Your Role in Project	Co-investigator (PI of the subcontract to WCMC)	
% Effort	5%	

Source	NCI (U10CA 180882) subcontract Alliance	
Amount	\$93,009	
Duration	04/2014 to 02/2019	
Principal Investigator	Dan Sargent	
Your Role in Project	Co-investigator (PI of the subcontract to WCMC)	
% Effort	20%	

Source	SU2C
Amount	\$13,515
Duration	08/2017 - 06/2020
Principal Investigator	Lewis Cantley
Your Role in Project	Co- Investigator
% Effort	5%

Source	National Institutes of Health 1UL1TR002384-01
Amount	\$5,319,707
Duration	09/2017 to 06/2022
Principal Investigator	Julianne Imperato-Mcginley
Your Role in Project	Co-Investigator
% Effort	6%

Source	NCI (5U54CA 168512) SARC Sarcoma SPORE
Amount	\$97,045
Duration	09/2016 to 08/2018
Principal Investigator	Laurence Baker, Raphael Pollock, Denise Reinke
Your Role in Project	Principal Investigator (Subcontract)
% Effort	5%

Source	Prostate Cancer Foundation
Amount	\$1,000,000
Duration	7/2017 to 8/2018
Principal Investigator	Scott Tagawa
Your Role in Project	Co-Investigator
% Effort	5%

Source	Department of Defence (Subcontract with Duke University)
Amount	\$170,266
Duration	11/2017 to 10/2020
Principal Investigator	David Harpole
Your Role in Project	Principal Investigator (Subsite)
% Effort	10%

# I. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

i.e. – Journal Reviewer, Editorial Boards, Study Sections, Invited Presentations

Activity / Responsibility	Dates
Reviewer	1991 to 1999
The American Math Monthly	
Gender and Ethnic Division Committee Member	2002 to 2005
North Central Cancer Treatment Group	
Neuro-Oncology Committee Member	2002-2006
North Central Cancer Treatment Group	
Reviewer	1994 to 1999
The American Statistician	
Editorial board member	1998 to 2003

Lawrent of Obstitution ("Acception	
Journal of Statistics Education Reviewer	2001 to 2004
Mayo Clinic Proceedings	2001 10 2004
Reviewer	2003 to 2006
Circulation	2003 to 2000
NCI Review Panel Member	
Consortium Therapeutic Studies of Primary Central Nervous System	2003, 2008
Malignancies in Adults	2003, 2006
Reviewer	2004 to present
Bioinformatics	2004 to present
NCI Study Section ad hoc Member	2004, 2007, 2008
Scientific Review Group Subcommittee H-Clinical	2004, 2007, 2008
Reviewer	2004 to present
Cancer Research	2004 to present
Editorial Board	20045-2014
Neuro-Oncology	200 10 2014
Reviewer	2005 to 2006
American Journal of Gastroenterology	2000 10 2000
Review Panel Member	2005
Academic Public-Private Partnership Program (AP4)	
NCI-Avon Foundation Review Panel Member	2005 to 2006
PFP Awards Program	
NCI Review Panel Member	2006
Advanced Proteomic Platforms and Computation Sciences for the NCI Clinical	12000
Proteomic Technologies Initiative Review Panel	
Executive Committee Member	2006 to 2012
American College of Surgeons Oncology Group	2000 10 20 12
NCI Committee Member	2007 to 2009
Breast Cancer Intergroup Committee	200. 10 2000
NCI Committee Member	2008 to 2009
Breast Cancer Intergroup Correlative Sciences Committee	2000 10 2000
NCI Study Section Member	2009 to 2012
Scientific Review Group Subcommittee H-Clinical	
NCI Steering Committee Member	2009-2013
Gastrointestinal Stromal Tumor Working Group	
NCI Steering Committee Member	2009 to present
Brain Malignancies	·
NCI Review Panel Member	2006
Novel Methodologies	
Data Monitoring Committee Member	2006 to 2011
American College of Surgeons Oncology Group	
Breast Cancer Committee Lead Statistician	2006 to 2011
American College of Surgeons Oncology Group	
Reviewer	2006
Biometrics	
NIAID Review Panel Member	2006
Cooperative Study Group for Autoimmune Disease Prevention	
Clinical Scientific Review Committee Member	2006 to 2011
American College of Surgeons Oncology Group	
Reviewer	2006 to present
International Journal of Cancer	
NICHHD Review Panel Member	2007
Obstetrical Pharmacology Research Network-Data Coordination and Analyses	
Center (OPRU-DCAC)	
Canada Cancer Society Review Panel	2007
Grant Application Review	
Editorial Board	2007 to 2010
Journal of Clinical Oncology	
NIAID Review Panel Member	2008
1909	

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Proteomics Centers for Infectious Diseases and Biodefense	
NIDDK Review Panel Member Hepatitis B Clinical Research Network (U01)	2008
NIH Review Panel Member	2008
Data Management and Coordinating Center DMCC for the Rare Diseases Clinical	
Research Network (RDCRN)	
NIDDK Review Panel Member	2008
Multi-disciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research	2000
Network (U01)	
Data Monitoring Committee Member	2008-2012
Astra-Zeneca Phase III Trial	2000 2012
Reviewer	2008 to present
EURASIP Journal on Bioinformatics and Systems Biology	2000 to present
NCI Committee Member	2008 to 2009
Clinical Trials Advisory Committee, Operational Efficiencies Working Group	2000 to 2009
NICHHD Review Panel Member	2009
Best Pharmaceuticals for Children Act Data Coordinating Center	2009
	2009
MN Partnership for Biotechnology and Medical Genomics Review Panel Member	2009
Scientific review of grant proposals	0000
NIDA Review Panel Member	2009
Data and Statistics Center for NIDA Clinical Trials Network	
Thoracic Cancer Committee Lead Statistician	2009 to 2011
American College of Surgeons Oncology Group	
Reviewer	2009 to present
British Journal of Cancer	
Reviewer	2009 to present
Clinical Trials	
Reviewer	2009 to present
Plos1	
NCI Review Panel Member	2010
Clinical Proteomic Technologies for Cancer Initiative: Proteome Characterization	The second second
Centers	
NICHHD Review Panel Member	2010
Pediatric Trials Network	
Review Panel Member	2010
National Cancer Institute of Canada	
DOD CDMRP Review Panel Member	2010, 2011, 2012
Prostate Cancer Research Program	
Data Monitoring Committee Chair	2010 to 2014
University of Minnesota Iron Study	
Data Monitoring Committee Member	2010 to 2014
Eli Lilly 14T-MC-JVBB Trial	
Data Monitoring Committee	2010 to 2014
Incyte RESPONSE Trial	
Associate Editor	2010 to 2017
Journal of Clinical Oncology	
Deputy Editor	2017-present
Journal of Clinical Oncology	
Reviewer	2010, 2013, 2017
Nature	
NICHHD Review Panel Member	2011
Systematic Review of Neonatal Medicine	
NICHHD Review Panel Member	2011
Maintenance of Child Health and Development Studies Name and Address Files	
Dutch Cancer Society Review Panel Member	2011, 2014, 2015
Scientific Grant Review	
Reviewer	2011 to present
Annals of Surgery	
Operations Committee Member	2011 to 2015
Operations Committee Member	2011102010

Alliance Adult Cancer Cooperative Group	
Scientific Concept Peer Review Committee Member	2011 to 2014
Alliance Adult Cancer Cooperative Group	2017 10 2017
Data Safety Monitoring Board Chair	2011 to present
Kanas University PAD in AA Trial	
NICHHD Review Panel Member	2012
Folic Acid Supplementation and Semen Quality Trial (FAAST)	
NIAID Review Panel Member	2012
Pre-Clinical Pharmacology and Toxicology Studies	
NCI Review Panel	2012
Pre-clinical Efficacy and Intermediate Endpoint	2040 2044
NIDA Review Panel	2012, 2014
Data, Statistics, and Clinical Trial Support for NIDA  Cancer in the Elderly Committee Lead Statistician	2012 to 2015
Alliance Adult Cancer Cooperative Group	2012 10 2015
NICHHD Review Panel Member	2013
Multiple Study Data Coordinating Center for DESPR	2013
Mayo Clinic Review Panel Member	2013
Microbiome Program Clinic Trial Funding	2010
DOD CDMRP Review Panel Member	2013, 2015
Psychological Health/Traumatic Brain Injury Research Program	
NICHHD Review Panel Member	2013
Further Investigation into the Causes of Stillbirth Concept Clearance	
Publications Committee Member	2013 to 2016
Alliance Adult Cancer Cooperative Group	
Neuro-Oncology Committee Lead Statistician	2013 to present
Alliance Adult Cancer Cooperative Group	
FDA Medical Devices Advisory Committee Member	2013 to present
General and Plastic Surgery Devices	
Damon Runyon Foundation Review Panel Member	2013 to present
Clinical Investigator Award	0044 0045
NCI Review Panel Member	2014, 2015
PLCO Secondary Studies Proposals  NIAID Review Panel Member	2014
Inner City Asthma Consortium (ICAC3)	2014
DOD CDMRP Review Panel Member	2014
Vision Research Program	2014
Associate Editor	2014 to present
Neuro-Oncology	25 1 1 15 process.
Data Safety and Monitoring Board Committee Member	2014 to present
NIDDK	
NICHHD Review Panel Member	2015
P01 Pre-Natal Microbiome Grant Review	
NIAID Review Panel Member	2015
Centers for Medical Countermeasures against Radiation Consortium (U19	
U.S. Army and the Army Medical Research and Material Command Review Panel	2015
Army Broad Agency Announcement (BAA)	
Cancer Research UK Review Panel Member	2015
Biomarker Project Award	2015 2018
DOD CDMRP Review Panel Member	2015-2018
Statistical Associate Editor	2015 to present
American Journal of Respiratory and Critical Care Medicine  NIAMS Technical Evaluation Panel Member	2016
	2016
Clinical Studies Management and Support  NIAID Scientific Review Panel Member	2016
Asthma and Allergic Diseases Cooperative Research Centers	2010
NICHD Technical Evaluation Panel Member	2016
Best Pharmaceutical for Children Act Data Coordinating Center	20.0
NINDS Scientific Review Panel Member	2016
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#### J. PROFESSIONAL MEMBERSHIPS

Include medical and scientific societies.

Member/Officer/Fellow/Role	Organization	Dates
Member	Operations Research Society of America	1990 to 1993
Officer	Operations Research Society of America	1992
Member	Mathematical Association of America	1991 to 1997
Officer	American Statistical Association	2000 to 2003; 2011 to 2013
Member	American Society of Clinical Oncology	2005 to present
Member	International Biometric Society, East North American Region	2006 to present
Officer	International Biometric Society, East North American Region	2008 to 2011
Member	Society of Clinical Trials	2008 to present

#### K. HONORS AND AWARDS

Name of award	Date awarded
Pi Mu Epsilon (Math honorary) - Macalester College	1980
Phi Beta Kappa - Macalester College	1982
Magna Cum Laude - Macalester College	1983
Academic All-American, Division III Volleyball - Macalester College	1983
Fredrick Hennie II Teaching Award - Massachusetts Institute of Technology	1987
Health Sciences Research Distinguished Teaching Award - Mayo Clinic	2004
Macalester College Distinguished Alumni in Science	2015

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## Exhibit 141

UNITED STATES DISTRICT COURT  DISTRICT OF NEW JERSEY	DISTRICT OF NEW JERSEY  TIN RE JOHNSON & JOHNSON ) MDL No.  TALCUM POWDER PRODUCTS ) 16-2738 (FLW)(LOMARKETING SALES PRACTICES, )  AND PRODUCTS LIABILITY )  LITIGATION )  THIS DOCUMENT RELATES TO )  ALL CASES )  VIDEOTAPED DEPOSITION OF  GREGORY B. DIETTE, M.D.  TOWSON, MARYLAND  TUESDAY, APRIL 9, 2019	DISTRICT OF NEW JERSEY  THE JOHNSON & JOHNSON   MDL No.  TALCUM POWDER PRODUCTS   16-2738 (FLW)(LOMARKETING SALES PRACTICES,   AND PRODUCTS LIABILITY   DOMESTION   DOMESTION	DISTRICT OF NEW JERSEY  TALCUM POWDER PRODUCTS ) 16-2738 (FLW)(LEMARKETING SALES PRACTICES, )  AND PRODUCTS LIABILITY )  LITIGATION )  THIS DOCUMENT RELATES TO )  ALL CASES )  VIDEOTAPED DEPOSITION OF  GREGORY B. DIETTE, M.D.  TOWSON, MARYLAND  TUESDAY, APRIL 9, 2019	DISTRICT OF NEW JERSEY  THE JOHNSON & JOHNSON   MDL No.  TALCUM POWDER PRODUCTS   16-2738 (FLW)(LOMARKETING SALES PRACTICES,   AND PRODUCTS LIABILITY   DOMESTION   DOMESTION		Pag
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Gregory B. Diette, M.D.

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1	Deposition of GREGORY B. DIETTE, M.D., held at	1 APPEARANCES	(Continued):
2	the:	2	
3		3 CYNTHIA L.	GARBER, ESQUIRE
4		4 ROBINSON C	CALCAGNIE, INC.
5	SHERATON BALTIMORE NORTH HOTEL	5 19 Corporate I	Plaza Drive
6	903 Dulaney Valley Road	6 Newport Beac	h, California 92660
7	Towson, Maryland 21204	7 (949) 720-128	8
8		8	
9		9 NATHAN D. 1	FINCH, ESQUIRE
10		10 MOTLEY RIC	CE LLC
11		11 401 9th Street,	, NW
12		12 Suite 1001	
13		13 Washington, Γ	
14		14 (202) 232-550	7
15		15	
16	Pursuant to notice, before Leslie Anne Todd,		THE JOHNSON & JOHNSON DEFENDANTS:
17	Court Reporter and Notary Public of the State of		BROWN, ESQUIRE
18 19	Maryland, who officiated in administering the oath		. HEASLIP, ESQUIRE
20	to the witness.	<ul><li>WEIL, GOTSI</li><li>17 Hutfish Street</li></ul>	HAL & MANGES LLP
21			
22		22 (609) 986-110	w Jersey 08542-3792
23		23	•
24		24	
25		25	
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1	APPEARANCES	1 APPEARAN	NCES (Continued):
2		2	
3	ON BEHALF OF THE PLAINTIFFS:	3 KATHE	RINE MCBETH, ESQUIRE
4	MICHELLE PARFITT, ESQUIRE		ER BIDDLE & REATH, LLP
5	ADAM K. ROSEN, ESQUIRE	_	gan Square, Suite 2000
6	ASHCRAFT & GEREL, LLP	•	phia, Pennsylvania 19103-69896
7	1825 K Street, N.W.	7 (215) 98	8-2706
8	Suite 700	8	A D AMILED ESSUEDE
9	Washington, D.C. 20006		A D. MILLER, ESQUIRE
10	(202) 783-6400		EN, ARPS, MEAGHER & FLOM, LLP
11 12	CUDICTORHED WITH ECOLURE		w York Avenue, N.W.
13	CHRISTOPHER V. TISI, ESQUIRE LEVIN PAPANTONIO THOMAS MITCHELL	12 Wasning 13 (202) 37	gton, D.C. 20005
14	RAFFERTY PROCTOR, P.A.	13 (202) 37	1-/000
15	316 South Baylen Street		LF OF THE PCPC:
16	Pensacola, Florida 32502		AS T. LOCKE, ESQUIRE
17	(850) 435-7000		RTH SHAW LLP
18	(000) 100 7000		reet, N.W.
19	DENNIS M. GEIER, ESQUIRE		gton, D.C. 20004-1454
20	COHEN PLACITELLA ROTH, PC	20 (202) 463	
21	127 Maple Avenue	21	
22	Red Bank, New Jersey 07701	22 ALSO PRE	SENT:
23	(732) 747-9003		L HOLMSTOCK, Videographer
24		24	
25		25	
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4 (Pages 10 to 13)

1 Q All right. Now, you're sitting here 2 today in Towson, Maryland, in a Sheraton Hotel; is 3 that correct? 4 A That is. 5 Q All right. You are normally, I believe, 6 over at Johns Hopkins University Medical Center, 7 correct? 8 A That's right. 9 Q All right. Is your department aware of 10 the fact that you're sitting over here having a 11 deposition taken? 12 A I don't know if anybody knows about this 13 today, but they wouldn't be surprised, I mean, to 14 Defendants' Response to the Plaintiffs' Documen 15 Q All right. They know that you 16 frequently give depositions so they would not be 17 A Yes.  Q All right. Have you had a chance to review that? 4 A I have. 5 Q All right. How recently? 6 A Last week sometime. 7 Q All right. Was it provided to you by 8 counsel? 9 A I think that's the only way I could get 10 it. 11 Q Okay. Very good. 12 Now, yesterday, perhaps early in the 13 morning, I was also provided a copy of the 14 Defendants' Response to the Plaintiffs' Documen 15 Q All right. They know that you 16 Videotaped Deposition.	Ī	Page 14		Page 16
2 Q Good Worning, Fine, thanks. 4 Q Good. We will dispense with the usual 5 comments with regard to a deposition. I 6 understand you've back on the mic. 7 THE VIDEOGRAPHER: Microphone. 8 BY MS. PARFITT: 10 Dr. Diette, we'll dispense with the 11 usual comments with regard to a deposition is 12 about. I understand you've probably had your 13 deposition taken more than a hundred times. Is 14 that fair? 15 A I don't know if it's a hundred, but — 16 but plenty enough that I think that I — I 17 understand the process. 18 Q All right. The only one that I will ask 19 you to pay some attention to is the fact that if 20 you don't understand my question, please let me 21 know. Otherwise, I'm going to assume you 22 understand every question that I ask, and the 23 answers that you're giving are truthful and 24 accurate. Fair enough? 25 A I tis.  Page 15  Page 15  Q All right. Now, you're sitting here 2 today in Towson, Maryland, in a Sheraton Hotel; is 3 that correct? 4 A That is. 5 Q All right. You are normally, I believe, 6 over at Johns Hopkins University Medical Center, 7 correct? 8 A That's right. 9 Q All right. Is your department aware of 10 the fact that you're sitting over here having a 11 deposition taken? 12 A I don't know if anybody knows about this 12 today, but they wouldn't be surprised, I mean, to 13 fright. They know that you 14 fright. How recently? 15 A I faight. They know that you 16 frequently but they know that you 17 G D, Diette, ethin that's the only way I could get 18 it. 19 G Okay. Very good. 20 Okay. Very good. 30 Okay. Very good. 31 Tight. How recently? 4 A That's tight. Gove have a sent that do give 4 deposition taken? 4 A That's tight. Gove have a sent that one to review that? 4 A That's right. 5 Q All right. How recently? 5 A Last week sometime. 5 Q All right. How wouldn't be surprised, I mean, to 5 Q All right. They know that - that I do give 6 deposition taken? 6 G C Reposition sken? 7 C Dr. Diette, let me present you with a 6 C Reposition sken? 8 A That's the only way I could get 8 it. 9 Q O	1	BY MS. PARFITT:	1	jury.
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THE VIDEOGRAPHER: Microphone.  BY MS. PARFITT:  BY MS. PARFITT:  BY MS. PARFITT:  BY MS. PARFITT:  THE WITNESS: My parents gave it to n for what it's worth, but it's Gregory Bruce Diette.  BY MS. PARFITT:  BY MS. PARFITT:  Q O. Okay. Very good.  Dr. Diette, we'll dispense with the should be a deposition is about. I understand you've probably had your deposition taken more than a hundred times. Is that fair?  A I don't know if it's a hundred, but—but plenty enough that I think that I—I to but plenty enough that I think that I—I to understand the process.  A I don't know if it's a hundred, but—but plenty enough that I think that I—I to understand the process.  BY MS. PARFITT:  Q O All right. The only one that I will ask you to pay some attention to is the fact that if you to pay some attention to is the fact that if you condoint understand my question, please let me when you carried the process.  A I tis.  Page 15  Q All right. Now, you're sitting here today in Towson, Maryland, in a Sheraton Hotel; is that correct?  A That is.  Page 15  Q All right. Now, you're sitting here today in Towson, Maryland, in a Sheraton Hotel; is that correct?  A That is.  Q All right. You are normally, I believe, over at Johns Hopkins University Medical Center, correct?  A That's right.  Q All right. Syour department aware of the fact that you're string over here having a deposition taken?  A I don't know if anybody knows about this today, but they wouldn't be surprised, I mean, to hear it if I told them.  A B BROWN: Objection to form.  THE WITNESS: They—I don't know about frequently give depositions so they would not be surprised; is that correct?  BY MS. PRAFITT:  Q All right. Dr. Diette, what I'd like to do is mark as Exhibit No. 1 was marked for identification.)  BY MS. PRAFITT:  Q Dr. Diette, khat I's like this. Or, in the motice of deposition. Have you seen that docum because the back of the deposition, there is a notice that —there is a request for you to bring certain information to your deposition? Do you see that?  A I have	6		6	<del>-</del>
8 BY MS. PARFITT: 9 Q All right. Now we're back on the mic. 10 Dr. Diette, we'll dispense with the 11 usual comments with regard to what a deposition is about. I understand you've probably had your 12 about. I understand you've probably had your 13 deposition taken more than a hundred times. Is 14 that fair? 15 A I don't know if it's a hundred, but — 16 but plenty enough that I think that I — I 17 understand the process. 18 Q All right. The only one that I will ask 19 you to pay some attention to is the fact that if 20 you don't understand my question, please let me 21 know. Otherwise. The going to assume you 22 understand every question that I ask, and the 23 answers that you're giving are truthful and 24 accurate. Fair enough? 25 A It is.  Page 15  Page 15  Q All right. Now, you're sitting here 2 today in Towson, Maryland, in a Sheraton Hotel; is 3 that correct? 4 A That is. 5 Q All right. You are normally, I believe, 6 over at Johns Hopkins University Medical Center, 7 correct? 8 A That's right. 9 Q All right. Is your department aware of 10 the fact that you're sitting over here having a 11 deposition taken? 12 A I don't know if anybody knows about this 13 today, but they wouldn't be surprised, I mean, to 14 hear it if I told them. 15 Q All right. They know that you 16 frequently give depositions so they would not be 17 surprised; is that correct? 18 MS. BROWN. Objection to form. 19 MS. BROWN. Objection to form. 20 Q All right. Very good. 21 depositions. 22 BY MS. PARFITT: 23 Q All right was it provided to you we see that docum before? 24 All right. Have you seen that docum before? 25 All right. Was it provided to you by counse? 26 Correct? 27 A Yes. 28 Q All right. Have you had a chance to review that? 39 A That's right. 40 A That is. 41 A I think that's the only way I could get it. 41 Correct? 42 A I think that's the only way I could get it. 43 Correct? 44 A That is. 55 Q All right. They know that you 56 Freq				
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	Page 18		Page 20
1	your responses to the requests that were	1	much.
2	propounded upon you to for documents and other	2	BY MS. PARFITT:
3	materials prior to your deposition, correct?	3	Q All right. Dr. Diette, number or
4	MS. BROWN: Objection to the form. It	4	Exhibit No. 3, the first document, Supplemental
5	represents the lawyer's objections to the document	5	Materials Reviewed and Considered, did you prepare
6	requests you served.	6	this Supplemental Materials Reviewed and
7	MS. PARFITT: Fair.	7	Considered?
8	THE WITNESS: I I think Ms. Brown's	8	A I contributed to it, but I didn't do the
9	got it right.	9	typing.
10	BY MS. PARFITT:	10	Q Okay. What does that mean when you say
11	Q All right. Did you well, let's have	11	you contributed to it?
12	marked the attachment to the response to	12	A I helped to clarify what other
13	plaintiffs' document, which was prepared by your	13	because this this looks like it's all
14	lawyers. And let's separately mark as Exhibit	14	reports I just want to make sure what's here
15	No. 3 the attachments, if you will.	15	reports, a couple of papers probably, and I I
16	A Should I pull this apart or or you	16	helped to verify that these were also things that
17	want to do that?	17	I had had received and had a chance to look at.
18	Q And for purposes of the record,	18	Q All right. So would it be fair to say
19	Exhibit 2 will represent the entire document, the	19	that the 23 items listed on this were materials
20	response to plaintiffs' request, and No. 3 will	20	that somebody typed on a list and asked that you
21	represent just the attachments to the request,	21	review it; is that correct?
22	which would be material that you, Dr. Diette, were	22	MS. BROWN: Objection to the form.
23	to provide.	23	Misstates his testimony.
24	(Diette Exhibit No. 3 was marked	24	THE WITNESS: So I think, just in terms
25	for identification.)	25	of the sequence, I mean I've gotten materials in
23	To recitification.)		of the sequence, I mean I ve gotten materials in
	Page 19		Page 21
1	BY MS. PARFITT:	1	this matter over a period of time, right. So they
2	Q And we'll briefly just review what's	2	come in dribs and drabs. And a lot of this looks
3	here, so we can move on to other areas.	3	like some of the more recent things that came, you
4	The first page of that document	4	know, because you guys have been doing
5	indicates supplemental materials reviewed and	5	depositions, and some of the reports came in later
6	considered.	1	
O		6	•
7	MS. BROWN: Counsel, can we go off the	6 7	and so forth. So it's really that's how I got
	MS. BROWN: Counsel, can we go off the record for a second?		and so forth. So it's really that's how I got the materials, and then this is just to make sure
7		7	and so forth. So it's really that's how I got
7 8	record for a second?	7 8	and so forth. So it's really that's how I got the materials, and then this is just to make sure that I had a complete list of everything that I've
7 8 9	record for a second?  MS. PARFITT: Yes.	7 8 9	and so forth. So it's really that's how I got the materials, and then this is just to make sure that I had a complete list of everything that I've gotten.
7 8 9 10	record for a second?  MS. PARFITT: Yes.  THE VIDEOGRAPHER: The time is 9:03.	7 8 9 10	and so forth. So it's really that's how I got the materials, and then this is just to make sure that I had a complete list of everything that I've gotten.  BY MS. PARFITT:  Q All right. And the reason I asked is
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	record for a second?  MS. PARFITT: Yes.  THE VIDEOGRAPHER: The time is 9:03.  We're going off the record.  (Pause in the proceedings.)  THE VIDEOGRAPHER: The time is 9:04 a.m.  We're back on the record.  MS. BROWN: Good morning. This is Ali  Brown for J&J. We're back on the record, having taken a short break to put the cameras on both the questioner and myself, and we'll proceed, of course, with the camera on Dr. Diette. Thank you.  MS. PARFITT: Thank you. And I should have asked, there's no one on the phone, is there, today?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	and so forth. So it's really that's how I got the materials, and then this is just to make sure that I had a complete list of everything that I've gotten.  BY MS. PARFITT:  Q All right. And the reason I asked is because you submitted your report on February 25th, 2019. So may I assume that everything on the list, Exhibit No. 3, the first page, supplemental, represents documents you received after February 25th, 2019, correct?  MS. BROWN: Objection to the form.  THE WITNESS: I wouldn't assume that. I mean, so certainly some things here, right. So the expert reports that are dated 2/25, I didn't have, you know, even on the day that I submitted mine, so those came after. Something like the

	Daga 22		Daga 24
	Page 22		Page 24
1	BY MS. PARFITT:	1	Q All right. Let me get this straight.
2	Q All right. Is it fair to say that the	2	Your hourly rate is 485.
3	items that are listed on Exhibit No. 2 3 were	3	A Well, sort of. I'll describe it if
4	not items that you considered for purposes of the	4	you'd like here.
5	opinions you've expressed in your report of	5	Q Well, I you can understand my
6	February 25th, 2019?	6	confusion. If your hourly rate is 485, I want to
7	MS. BROWN: Objection to the form.	7	know you're why I'm getting
8	THE WITNESS: So I it's very possible	8	A You don't need to be confused for very
9	that the Barnard study I did consider. Trabert, I	9	long, though.
10	can't remember. But definitely, right, the expert	10	MS. BROWN: Hold on. Hold on.
11	reports that are dated on 2/25, I couldn't have	11	Counsel, you've got to let him answer
12	considered. And anything that's a deposition	12	the question.
13	transcript that happened after 2/25, obviously I	13	MS. PARFITT: Sure.
14	couldn't have considered that either.	14	MS. BROWN: He is endeavoring to set
15	BY MS. PARFITT:	15	that straight.
16	Q All right. Very good.	16	MS. PARFITT: Please.
17	The information thereafter, I believe we	17	MS. BROWN: So go ahead.
18	have one, two, three four invoices. They	18	THE WITNESS: I think it's pretty easy.
19	begin with the date of 12/14/2018, and end with a	19	I charge \$400 an hour, and Medical Science
20	date of 3/15/19.	20	Affiliates prepares this invoice, and part of
21	Are there any other invoices that you	21	their business model is to add an hourly rate
22	would like to share with me today?	22	to to my rate.
23	A I don't have any others that I'm aware	23	BY MS. PARFITT:
24	of.	24	Q Okay. And I want to talk a little bit
25	Q Are you preparing any invoices for your	25	about that in a moment, but that's exactly one of
	Page 23		Page 25
		1	1436 23
1	time post the very last invoice which is dated	1	the issues I need some clarification on. But
1 2	time post the very last invoice which is dated 3/15/2019?	1 2	
			the issues I need some clarification on. But
2	3/15/2019?	2	the issues I need some clarification on. But let's finish up the bills.
2	3/15/2019? A I will be.	2 3	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.
2 3 4	3/15/2019?  A I will be.  Q All right. How many hours have you	2 3 4	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for
2 3 4 5	3/15/2019?  A I will be.  Q All right. How many hours have you spent since your submitting the invoice of	2 3 4 5	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for \$17,103.75. Correct?
2 3 4 5 6	3/15/2019?  A I will be.  Q All right. How many hours have you spent since your submitting the invoice of 3/15/2019?	2 3 4 5 6	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for \$17,103.75. Correct?  A Correct.
2 3 4 5 6 7	3/15/2019?  A I will be.  Q All right. How many hours have you spent since your submitting the invoice of 3/15/2019?  A Let's see, three I would estimate	2 3 4 5 6 7	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for \$17,103.75. Correct?  A Correct.  Q And we have a bill for 1/15/2018 for
2 3 4 5 6 7 8	3/15/2019?  A I will be.  Q All right. How many hours have you spent since your submitting the invoice of 3/15/2019?  A Let's see, three I would estimate about about 20 hours or maybe 25 hours, give or	2 3 4 5 6 7 8	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for \$17,103.75. Correct?  A Correct.  Q And we have a bill for 1/15/2018 for \$5,068.02, correct?
2 3 4 5 6 7 8	3/15/2019?  A I will be.  Q All right. How many hours have you spent since your submitting the invoice of 3/15/2019?  A Let's see, three I would estimate about about 20 hours or maybe 25 hours, give or take.	2 3 4 5 6 7 8	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for \$17,103.75. Correct?  A Correct.  Q And we have a bill for 1/15/2018 for \$5,068.02, correct?  A That's correct.  Q We have a bill for 2/12/2019 for
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2 3 4 5 6 7 8 9 10 11 12 13	3/15/2019?  A I will be.  Q All right. How many hours have you spent since your submitting the invoice of 3/15/2019?  A Let's see, three I would estimate about about 20 hours or maybe 25 hours, give or take.  Q All right. And what is your hourly rate?  A So to clarify, so when on here it says it's 485, my my rate itself is actually \$400 an	2 3 4 5 6 7 8 9 10	the issues I need some clarification on. But let's finish up the bills.  A Mm-hmm.  Q We have a bill for 12/14/2018 for \$17,103.75. Correct?  A Correct.  Q And we have a bill for 1/15/2018 for \$5,068.02, correct?  A That's correct.  Q We have a bill for 2/12/2019 for \$35,375. Is that correct?
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1	Q Now, attached to that is it has an	1	that I just made as I was reading through
2	exhibit on it, Plaintiffs' Exhibit No. 7, and it	2	different articles.
3	appears to be several pages of notes.	3	Q Okay. Would
4	Do you see that?	4	A No, I'm sorry.
5	A I do.	5	Q Are you finished?
6	Q All right. What are these notes?	6	A No, that's just what I was going to say,
7	A Well, these I haven't looked to see	7	so these are it just represents just notes that
8	for sure what's	8	I was making at certain times when I was looking
9	MS. BROWN: And, Counsel, just to make	9	at some of the articles.
10	sure the record is clear, this was produced in	10	Q Okay. When did you first start looking
11	response per your request for his notes that were	11	at any of the articles?
12	marked at the Ingham deposition. So this exhibit	12	A Sometime in by if we're talking
13	number is the marking from the Ingham deposition,	13	about the articles, meaning articles pertaining to
14	and these were the notes that he produced there	14	ovarian cancer and talcum powder, is it?
15	that I'm frankly sure you have access to, but in	15	Q Well, it's a good question, because you
16	the effort of cooperation, we reproduced them here	16	just said when you started looking at any of the
17	per your request.	17	articles, are you talk do these represent any
18	BY MS. PARFITT:	18	articles or do these represent articles of ovarian
19	Q So, Doctor	19	cancer and talcum powder?
20	A It's oh, go ahead. I'm sorry.	20	A Yeah, yeah.
21	Q Go ahead. You were going to tell me	21	MS. BROWN: And hold on, I think the
22	what they are.	22	record is going to be unclear. When you say
23	A Yeah, and I didn't know if that was	23	"these," are you referring to what has been marked
24	the the sufficient answer, because that's	24	as Plaintiffs' Exhibit 7 in response to your
25	literally, I guess, what they are right there.	25	MS. PARFITT: Correct.
	Page 27		Page 29
1		1	
1 2	These are they're an exhibit. But did you mean	1 2	MS. BROWN: notice of deposition?
	These are they're an exhibit. But did you mean something else, like		
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1 Q All right. So you would put a sticker on a paper like when I wanted to put a quote in, and then I tore it off.  4 Are these medical records that — or excuse me, medical articles that you were reviewing?  7 A These are scientific articles, yeah, the one state informed your report at your office, at your home?  10 Scientific and medical articles that informed your report at your office, at your home?  11 A I've gort — I've got little piles of 1 stuff everywhere you can look.  12 A I've gort — I've got little piles of 1 stuff everywhere you can look.  13 Suff everywhere you can look.  14 Q Okay. Do any of them have markings on them or any stickies and any stickies and any stickies and a full don't think there's any stickies and any stickies and any stickies and a full don't think there's any stickies and any stickies and a full don't think there's any stickies and any stickies any stickies and any stickies any sticki		Page 20		Dago 22
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	Page 34		Page 36
1	Q And we're going to talk about Medical	1	THE WITNESS: I've seen I've seen it
2	Science in just just a moment.	2	ranked highly. I don't remember if it was fifth,
3	Anything else other than the documents	3	but I've seen it ranked highly.
4	that I have in front of you, Exhibit 7, the	4	BY MS. PARFITT:
5	invoice and your supplemental reliance, that you	5	Q All right. Are you aware of the fact
6	have brought to your deposition today?	6	that ovarian cancer accounts for more deaths than
7	A So I didn't bring this today.	7	any other cancer in the female reproductive
8	Q Okay. Fair enough.	8	system?
9	A I mean I I didn't bring anything I	9	A Ovarian cancer. Is that is that a
10	mean I didn't bring any materials to the	10	statement from a like a document or something?
11	deposition.	11	Q It's a question.
12	Q Okay.	12	A It's a question that
13	All right. Dr. Diette, what is your	13	Q Do you know whether or not ovarian
14	profession?	14	cancer accounts for more deaths than any other
15	A Well, I'm a physician, epidemiologist,	15	cancer of the female reproductive system?
16	researcher.	16	A I know it's a highly ranked one. I
17	Q Okay. You're actually a professor of	17	wouldn't be able to say whether it's more than all
18	medicine at the Department of Pulmonary and	18	others.
19	Critical Care, is that correct, at Johns Hopkins?	19	Q All right. Do you know whether
20	A Literally it's the Department of	20	approximately 22,000 new cases of ovarian cancer
21	Internal Medicine, and it's the Division of	21	identified each year and 14,000 women
22	Pulmonary, Critical Care, and Sleep Medicine.	22	approximately will die in the United States alone
23	Q Okay. Dr. Diette, do you agree that	23	from ovarian cancer?
24	ovarian cancer ranks as the fifth cause of	24	MS. BROWN: Objection to the form.
25	neoplastic death among women?	25	THE WITNESS: I haven't memorized
	Page 35		Page 37
1	Page 35  A I've seen I've seen it listed on	1	Page 37 anything with exact numbers like that. I mean I'm
1 2	_	1 2	
	A I've seen I've seen it listed on		anything with exact numbers like that. I mean I'm
2	A I've seen I've seen it listed on you know, on lists of causes of death. I don't	2	anything with exact numbers like that. I mean I'm not saying it's far off from the truth, and if you
2 3	A I've seen I've seen it listed on you know, on lists of causes of death. I don't know what you mean by "agree with," but I mean	2 3	anything with exact numbers like that. I mean I'm not saying it's far off from the truth, and if you have, you know, some document that supports that,
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	Page 38		Page 40
1	MS. PARFITT: Ms. Brown, your objection,	1	thinking about your question before, I just wanted
2	according to the CMO in the MDL case, perhaps	2	to clarify that I because when you said that I
3	you're doing other state depositions, is that you	3	billed \$100,000, I think what you might be doing
4	say, "Objection. Form."	4	is adding up all of those MSA invoices, which that
5	And I'll try and do my best, if you'd do	5	doesn't all go to me. I mean there's a way to
6	the same. And I'm not admonishing you, and I hope	6	figure out how much that I've billed, but but
7	you're not admonishing me. That's not how I roll.	7	you wouldn't be correct if you're saying that
8	MS. BROWN: Well, the record is going to	8	those four invoices represent the amount that I've
9	be very clear	9	charged.
10	MS. PARFITT: It will be.	10	Q Okay. And we'll talk about that, but I
11	MS. BROWN: about the statement that	11	appreciate the clarification.
12	you just made about the other work that I'm doing.	12	So, the other question is, do you have
13	MS. PARFITT: I said	13	an understanding that most ovarian cancer cases
14	MS. BROWN: I am well aware of the	14	are detected and diagnosed at a late stage and
15	CMO	15	there are limited prospects for cure?
16	MS. PARFITT: Perfect. Okay.	16	MS. BROWN: Same objection.
17	Counsel	17	THE WITNESS: I have that general
18	MS. BROWN: and the deposition	18	understanding.
19	protocol in this case.	19	BY MS. PARFITT:
20	MS. PARFITT: that's fine.	20	Q Okay. Do you have any knowledge as to
21	MS. BROWN: And I	21	what the mortality and morbidity of ovarian cancer
22	MS. PARFITT: Counsel	22	is?
23	MS. BROWN: expect that you will	23	A Well, the morbidity is not a number,
24	abide by it	24	right. I mean you're talking about what are the
25	MS. PARFITT: let me ask questions.	25	consequences?
			Page 41
1	MS. BROWN: and not interrupt me.	1	Q You're right.
2	Thank you.	2	A And then the mortality would be
3	MS. PARFITT: I am not going to, but I	١ ,	<del>-</del>
		3	something that's an objective fact that there's a
4		4	something that's an objective fact that there's a percentage of people with the disease that die.
4 5	would ask the same courtesy. And, listen, we have		percentage of people with the disease that die.
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	Page 42		Page 44
1	BY MS. PARFITT:	1	Q Okay. All right. And we're going to
2	Q All right. Have you in the course of	2	talk about that in conjunction with just hold
3	strike that.	3	tight. I'm going to set that aside, and let me
4	All right. From a review of the	4	ask you this
5	materials you reviewed attached to your expert	5	A Can I ask just real quick?
6	report, Doctor, I see that you reviewed the Purdie	6	Q Sure.
7	case	7	A There's like a cold breeze blowing down
8	MS. BROWN: Counsel Counsel, is there	8	here, and I know we will regret making it warmer
9	a page you want to point him to so we can follow	9	in here at some point.
10	along?	10	Q Sure.
11	MS. PARFITT: I'm still asking the	11	MS. PARFITT: Well, let's take a moment
12	question, Counsel.	12	and let's see if we can
13	BY MS. PARFITT:	13	MS. BROWN: Why don't we go off the
14	Q Dr. Diette, attached to your report is a	14	record for one second.
15	materials reviewed. And on page 7, it lists that	15	THE VIDEOGRAPHER: The time is 9:25 a.m.
16	you have read the Purdie case, which is a 1995	16	We're going off the record.
17	case study excuse me, not case study, but a	17	(Pause in the proceedings.)
18	scientific article.	18	THE VIDEOGRAPHER: The time is 9:27 a.m.
19	MS. BROWN: Objection to the form.	19	and we are back on the record.
20	Take your time to get to that page,	20	(Diette Exhibit No. 4 was marked
21	Doctor.	21	for identification.)
22	THE WITNESS: It's 7 in my report?	22	MS. PARFITT: Ready?
23	BY MS. PARFITT:	23	THE VIDEOGRAPHER: Oh, yeah, we're on.
24	Q It is on page 7 of your report.	24	MS. PARFITT: Okay. Thank you.
25	MS. BROWN: And, Counsel, I think we	25	BY MS. PARFITT:
	Page 43		Page 45
1	have a disconnect here. Are you referring to the	1	Q Dr. Diette, let me show you what's been
2	7 of the reliance list?	2	marked as Plaintiffs' Exhibit No. 4 to the Diette
3	MS. PARFITT: I am. I'm sorry about	3	deposition, and I'll represent to you sorry
4	that.	4	I'll represent to you that this is the
5	THE WITNESS: Oh. Is it 7 of the the	5	MS. BROWN: Thank you.
6	exhibit you gave me or is it part of what's my	6	BY MS. PARFITT:
7	reliance list that's attached to my report?	7	Q an article by Dr. Purdie entitled
8	BY MS. PARFITT:	8	"Ovulation and Risk of Epithelial Ovarian Cancer"
9	Q What I have is your reliance list, and	9	published in the International Journal of Cancer
10		10	in 2003. Do you see that?
11	it's page 7 of your reliance list.  A I got you.	11	A I do.
12		12	
13	MS. BROWN: Got that. Okay. BY MS. PARFITT:	13	Q All right. If I can direct your attention to page 231 of that article.
13	Q And I believe you have three Purdie	14	MS. PARFITT: Let's put it on the ELMO.
14 15	excuse me, two Purdie cites, one 2003 and one	15	BY MS. PARFITT: Let's put it on the ELMO.
16	1995. Correct?	16	
16 17		17	Q Okay. And, Dr. Diette, I'll put it up on the overhead as well. About halfway down
18		18	there you go left-hand column, Dr. Purdie and
	Q Okay. Did you indeed review the Purdie article for purposes of your testimony here today?	19	authors state: "Thus, the latency period of more
19		20	authors state: "I hus, the latency period of more advanced malignant epithelial ovarian cancer could
20	MS. BROWN: Objection to the form.		
21	THE WITNESS: I don't think I reviewed	21	be estimated to be approximately 30 to 40 years."
	it for the purpose of my testimony, but I I	22 23	Did I read that correctly?  A You read it fine.
22	included it because it's semathing I marriages = -4		A YOUTEROULINE
23	included it because it's something I reviewed at		
	some point prior to preparing the report.  BY MS. PARFITT:	24 25	Q All right. Do you agree or disagree that the latency period of more advanced malignant

	Page 46		Page 48
1	epithelial ovarian cancer can be estimated to be	1	BY MS. PARFITT:
2	approximately 30 to 40 years?	2	Q Sure. And, you know, that might be
3	A Well, I think, you know so there's no	3	that might be fair. So let me go for a third try.
4	way for me to know for sure, right, but could	4	Okay?
5	be it seems like a pretty safe statement	5	A Okay.
6	because it could be more, it could be less.	6	Q Do you develop public health programs
7	It's also an incomplete sentence, right,	7	for Johns Hopkins?
8	in the sense that when you talk about the latency,	8	A I'm trying to think I would say
9	you talk about the latency between a particular	9	generally, no. I mean
10	kind of exposure. I mean, in this context, right,	10	Q It's not part of your role.
11	there may have other there may be other ways	11	MS. BROWN: Well, let him finish. I'm
12	people use that word, but in this context it's the	12	sorry.
13	time from the exposure to the development of the	13	THE WITNESS: But I don't know I
14	disease. So there's no exposure mentioned in that	14	mean, I don't know what I mean that's a pretty
15	sentence, so it's a little a little loose, you	15	broad topic, which is what's a public health
16	know.	16	program. So I'm just thinking like, for example,
17	MS. PARFITT: All right. Move to strike	17	you know, I've done work with asthma in in the
18	that last part of your statement.	18	inner city nearby.
19	BY MS. PARFITT:	19	BY MS. PARFITT:
20	Q Okay. Dr. Diette, do you agree that	20	O Correct.
21	it's imperative to develop public health programs	21	A And we certainly have a program, you
22	that either reduce the incidence or detect ovarian	22	know, that deals with with that. I wouldn't
23	cancer at an earlier stage?	23	say I've developed it as a public health program
24	A It's an agreeable statement.	24	per se but as a as a research program. But,
25	Q Okay. In developing public health	25	you know, where public health starts and stops,
23	Q Okay. In developing public heaten	23	you know, where public hearth starts and stops,
	Page 47		Page 49
1	Page 47 programs, does in order to set up preventive	1	I'm not exactly sure.
1 2		1 2	I'm not exactly sure.  Q Fair enough.
	programs, does in order to set up preventive		I'm not exactly sure.
2	programs, does in order to set up preventive programs, detection programs, does that include getting information about whatever the putative exposure may be to individuals who may be	2	I'm not exactly sure.  Q Fair enough.
2 3	programs, does in order to set up preventive programs, detection programs, does that include getting information about whatever the putative	2 3	I'm not exactly sure.  Q Fair enough.  All right. Talcum powder products are
2 3 4	programs, does in order to set up preventive programs, detection programs, does that include getting information about whatever the putative exposure may be to individuals who may be	2 3 4	I'm not exactly sure.  Q Fair enough.  All right. Talcum powder products are widely available, correct?
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Gregory B. Diette, M.D.

	Page 50		Page 52
1	Johnson & Johnson how many bottles of their Shower	1	BY MS. PARFITT:
2	to Shower they distributed?	2	Q Okay. Let me show you what I'll have
3	A No.	3	marked as Exhibit
4	MS. BROWN: Same objection.	4	MS. PARFITT: Where are we?
5	BY MS. PARFITT:	5	MR. ROSEN: Five.
6	Q All right. Have you ever purchased	6	BY MS. PARFITT:
7	talcum powder products?	7	Q 5. And I'll represent to you,
8	A I I don't do the shopping. You know,	8	Dr. Diette, that this is a bottle of Johnson's
9	and so it like, I don't I don't buy anything	9	Baby Powder, and we'll have it marked as Exhibit
10	at the store.	10	No. 5.
11	Q Okay. Fair enough.	11	(Diette Exhibit No. 5 was marked
12	Are you aware of the fact that Johnson &	12	for identification.)
13	Johnson continues to sell their talcum powder	13	BY MS. PARFITT:
14	products?	14	Q Now, my understanding is that you are
15	A I wasn't aware that they weren't. I	15	trained, skilled, and have expertise in pulmonary
16	mean, I don't know where I would get that from,	16	medicine, correct?
17	but as best as I can tell.	17	A Among other things.
18	Q All right. Have you ever looked at the	18	Q And I didn't mean to limit your
19	back of a Johnson & Johnson's Baby Powder product	19	expertise. Okay.
20	to see what it says about its usage	20	If you will, let me show pass to you
21	MS. BROWN: Objection.	21	the Exhibit No. 5, and ask that you turn it to the
22	BY MS. PARFITT:	22	back. Look at the bottle.
23	Q and direction?	23	MS. BROWN: Counsel, before he does
24	MS. BROWN: Excuse me. Objection to the	24	that, will you put represent on the record
25	form of the question.	25	where this bottle that you've marked as Exhibit 5
	Page 51		Page 53
1	THE WITNESS: It's possible that I have	1	
т —	THE WITNESS. It's possible that I have		
2		1	
2	years ago, but not not recently.	2	MS. PARFITT: Counsel, I'm asking the
3	years ago, but not not recently. BY MS. PARFITT:	2 3	MS. PARFITT: Counsel, I'm asking the questions. I just represent that it is a bottle
3 4	years ago, but not not recently.  BY MS. PARFITT:  Q Nothing recent.	2 3 4	MS. PARFITT: Counsel, I'm asking the questions. I just represent that it is a bottle of Johnson & Johnson's Baby Powder purchased from
3 4 5	years ago, but not not recently.  BY MS. PARFITT:  Q Nothing recent.  How about since you were retained by	2 3 4 5	MS. PARFITT: Counsel, I'm asking the questions. I just represent that it is a bottle of Johnson & Johnson's Baby Powder purchased from a store.
3 4 5 6	years ago, but not not recently.  BY MS. PARFITT:  Q Nothing recent.  How about since you were retained by Johnson & Johnson as an expert, have you ever	2 3 4 5 6	MS. PARFITT: Counsel, I'm asking the questions. I just represent that it is a bottle of Johnson & Johnson's Baby Powder purchased fror a store.  MS. MILLER: Michelle, I'm trying
3 4 5 6 7	years ago, but not not recently.  BY MS. PARFITT:  Q Nothing recent.  How about since you were retained by Johnson & Johnson as an expert, have you ever looked at a bottle of Johnson & Johnson's Baby	2 3 4 5 6 7	MS. PARFITT: Counsel, I'm asking the questions. I just represent that it is a bottle of Johnson & Johnson's Baby Powder purchased from a store.  MS. MILLER: Michelle, I'm trying really, really hard not to say a word today.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	years ago, but not not recently.  BY MS. PARFITT:  Q Nothing recent.  How about since you were retained by Johnson & Johnson as an expert, have you ever looked at a bottle of Johnson & Johnson's Baby Powder or Shower to Shower?  MS. BROWN: Same objection.  THE WITNESS: No. I've seen pictures, you know, in different settings, but I haven't I haven't seen a bottle of it or looked at it.  BY MS. PARFITT:  Q Okay. Do you have an understanding as to whether or not Johnson & Johnson's Baby Powder or the Shower to Shower contains a warning on its product against use in the genital area to avoid ovarian cancer?  MS. BROWN: Objection to the form.  THE WITNESS: I don't know whether they do or don't. But I'm also not, you know, skilled in warnings. So I wouldn't I mean, I even	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	questions. I just represent that it is a bottle of Johnson & Johnson's Baby Powder purchased from a store.  MS. MILLER: Michelle, I'm trying really, really hard not to say a word today.  MS. PARFITT: Sure.  MS. MILLER: I know that I'll annoy you  MS. PARFITT: Oh, no, you're not.  MS. MILLER: but it's not Johnson & Johnson's Baby Powder. It's Johnson's Baby Powder, and you keep saying it wrong.  MS. PARFITT: That's fine. That's fine.  MS. MILLER: And I think for the record, it's important. It's a product by JJCI, as you know.  MS. PARFITT: That's fine.  MS. MILLER: So we just need Johnson's  MS. PARFITT: Okay. And why don't we

	Page 54		Page 56
1	that it's Johnson's Baby Powder. Okay?	1	expert work for them?
2	MS. BROWN: And just to get my my	2	MS. BROWN: Objection to the form.
3	objection on the record to what you marked as	3	THE WITNESS: I believe so, yeah.
4	Exhibit 5, we have no representation of when this	4	BY MS. PARFITT:
5	was bought, by whom it was bought.	5	Q Okay. Had you ever worked for Johnson &
6	With that, Dr. Diette, here is	6	Johnson or any of their entities prior to 2017 in
7	Exhibit 5.	7	any type of litigation?
8	MS. PARFITT: Thank you.	8	MS. BROWN: Same objection.
9	BY MS. PARFITT:	9	THE WITNESS: I I don't think so. I
10	Q All right, Dr. Diette, look at the back	10	would say almost certainly no.
11	of that. Do you see that there's a little picture	11	BY MS. PARFITT:
12	that looks like a little baby with an X on it?	12	Q Okay. Since your retention in 2017, did
13	A I do.	13	Johnson & Johnson, their medical department, their
14	MS. BROWN: Objection to the form.	14	regulatory department, science department, ever
15	BY MS. PARFITT:	15	ask that you take a look at the back of the
16	Q Okay. Okay. What does that say on the	16	product, Johnson's Baby Powder, for purposes of
17	back of the product?	17	giving an opinion as to what scientific and
18	A It says: "Warning: Keep powder away	18	medical information should be on that product?
19	from child's face to avoid inhalation, which can	19	MS. BROWN: Objection to the form of the
20	cause breathing problems. Avoid contact with the	20	question.
21	eyes. For external use only."	21	THE WITNESS: I would be the wrong kind
22	Q Okay. And at the bottom of that	22	of expert for that. I mean I'm not a warnings
23	product, does it happen to say what's contained in	23	expert, so it wouldn't wouldn't make any sense
24	it?	24	for anybody to ask me that question.
25	MS. BROWN: Objection to the form of the	25	BY MS. PARFITT:
23	MB. BROWN. Objection to the form of the		B1 (46,174,011).
	Page 55		Page 57
1	question.	1	Q I'm not asking you about the adequacy of
2	THE WITNESS: It has a line called	2	the warning. I'm asking you about your expertise
3	"Ingredients," which says "Talc, fragrance."	3	as a pulmonary medicine expert with regard to
4	BY MS. PARFITT:	4	inhalation issues as contained on the back of that
5	Q Okay. Dr. Diette, you've been retained	5	product.
6	by Johnson & Johnson since when, for purposes of	6	A It still wouldn't make any sense. I
7	the ovarian cancer cases?	7	wouldn't be the person to ask that to.
8	MS. BROWN: Objection. Form. Do you	8	Q Dr. Diette, whether or not it makes
9	mean the Ingham case or do you mean the MDL?	9	sense to you or not, my question is simply this:
10	BY MS. PARFITT:	10	Yes or no, has Johnson & Johnson asked your
11	Q Well, let me clarify.	11	opinion at any point in time with regard to what
12	When were you first it's a fair	12	kind of scientific and medical information should
13	question when were you first retained by	13	be on the back of their powder?
14	Johnson & Johnson to represent them in either	14	MS. BROWN: Objection. Answered three
15	mesothelioma cases or ovarian cancer cases?	15	times.
	MS. BROWN: Objection to the form. He	16	THE WITNESS: They and everybody else in
16			the world has not asked me to do anything like
		17	the world has not asked the to do anything like
17	is an expert witness on behalf of Johnson &		
17 18	is an expert witness on behalf of Johnson & Johnson. He is not here representing anyone.	18	that ever.
17 18 19	is an expert witness on behalf of Johnson & Johnson. He is not here representing anyone. THE WITNESS: That honestly sounds like	18 19	that ever. BY MS. PARFITT:
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17 18 19 20 21 22 23 24	is an expert witness on behalf of Johnson & Johnson. He is not here representing anyone.  THE WITNESS: That honestly sounds like Ms. Brown's job, I mean, but but I guess to try to answer your question, the I was first asked to review the epidemiology in 2017.  BY MS. PARFITT:  Q Okay. And was that the first time that	18 19 20 21 22 23 24	that ever.  BY MS. PARFITT:  Q Okay. And they, Johnson & Johnson, has never asked you to your opinion with regard to the inhalation warning; is that correct?  MS. BROWN: Objection. Counsel, we've been through this like six times.
17 18 19 20 21 22 23	is an expert witness on behalf of Johnson & Johnson. He is not here representing anyone.  THE WITNESS: That honestly sounds like Ms. Brown's job, I mean, but but I guess to try to answer your question, the I was first asked to review the epidemiology in 2017. BY MS. PARFITT:	18 19 20 21 22 23	that ever. BY MS. PARFITT: Q Okay. And they, Johnson & Johnson, has never asked you to your opinion with regard to the inhalation warning; is that correct? MS. BROWN: Objection. Counsel, we've

	Page 58		Page 60
1	warning we're talking about, right?	1	you have who have a different opinion with regard
2	BY MS. PARFITT:	2	to the causality of talcum powder products and
3	Q The one that's on the back, yeah.	3	ovarian cancer?
4	A So it's still still the same.	4	MS. BROWN: Objection to the form.
5	Q Okay. And just for the record, we're	5	THE WITNESS: Well, I've seen like, for
6	going to put on the ELMO thank you. Just go	6	example, the expert reports that are that are
7	ahead and see if we can get that on there. Okay.	7	part of this matter and some of the deposition
8	(Counsel conferring.)	8	transcripts. So so, yes, I mean I've seen what
9	BY MS. PARFITT:	9	they've said.
10	Q And again, for clarity of the record,	10	BY MS. PARFITT:
11	what we've been talking about is on the child	11	Q Okay. And from your review of those
12	with the X over the nose and mouth and the warning	12	expert reports, do you understand that many of
13	that is to the far right, correct?	13	those scientists and epidemiologists are
14	MS. BROWN: Objection to the form.	14	individuals who treat women who have been
15	THE WITNESS: I was with you until you	15	diagnosed for ovarian cancer? Do you understand
16	said "to the far right." I don't know	16	that?
17	BY MS. PARFITT:	17	MS. BROWN: Objection. Lacks
18	Q To the right of the baby.	18	foundation, calls for speculation.
19	A Oh, I see. I'm sorry.	19	THE WITNESS: So I saw that there were
20	Q Yeah, no problem.	20	some GYN oncologists involved. I don't remember
21	A Yeah. No, that's	21	the count of them, but I saw there were GYN
22	Q That's what we're talking about.	22	oncologists, both on the defense and the
23	A It's to the right of the baby, yeah.	23	plaintiffs' side.
24	Q Okay. Very good. All right.	24	BY MS. PARFITT:
25	Dr. Diette, as a scientist and a	25	Q Okay. And the GYN oncologists would be
	Page 59		Page 61
1	clinician, do you have a belief or opinion that	1	the practice of medicine that treats women for
2	women should be informed of even a potential risk	2	reproductive diseases and cancers like ovarian
3	of using talcum powder products on their genital	3	cancer, correct?
4	area?		
	area:	4	MS. BROWN: Objection.
5	MS. BROWN: Objection.	4 5	MS. BROWN: Objection. THE WITNESS: They they would be the
5 6			<del>-</del>
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Gregory B. Diette, M.D.

	Page 62		Page 64
1	treat and care for women treat and care and	1	that.
2	provide gynecological and oncological care to	2	BY MS. PARFITT:
3	women who have been diagnosed with ovarian cancer?	3	Q Okay. What is your understanding of the
4	MS. BROWN: Objection to the form.	4	testing that's been performed by Johnson & Johnson
5	THE WITNESS: Mostly, no, although	5	on their talcum powder products?
6	I'll just there was a lot in your question,	6	MS. BROWN: Objection. That's overly
7	right, so that	7	broad.
8	BY MS. PARFITT:	8	THE WITNESS: Well, like the type
9	Q You want me to break it down?	9	MS. BROWN: You mean internal, external,
10	MS. BROWN: Let him finish first, and	10	third party, FDA?
11	then you can follow up. He has to be allowed to	11	BY MS. PARFITT:
12	answer your question.	12	Q Do you understand the question?
13	MS. PARFITT: Oh, absolutely, but if	13	A I was actually going to say something
14	it's unclear that was one of the	14	similar to what Ms. Brown said but less
15	THE WITNESS: I didn't say it was	15	sophisticated.
16	unclear. I just said it it's complicated, so	16	I mean what I meant was, were you asking
17	there's more than it's not just a simple	17	about like the kinds of tests that were done or
18	answer.	18	or things of that sort? I just I just know,
19	MS. PARFITT: Let me withdraw the	19	generally speaking, that there has been testing
20	question.	20	done.
21	MS. BROWN: Wait, Counsel, he's not	21	Q Sure. Let me make it very simple.
22	done.	22	Are you aware of studies strike that.
23	Dr. Diette, you finish your answer, and	23	Have you seen studies done by Johnson &
24	then counsel, of course, will follow up.	24	Johnson that tested and evaluated their talcum
25	BY MS. PARFITT:	25	powder products for the presence of asbestos?
			powers products for the presence of acceptable.
	Page 63		Page 65
1	Q Okay. Go ahead.	1	MS. BROWN: Same objection.
2			
	A Thank you.	2	THE WITNESS: I don't think I've seen
3	A Thank you. Q Sure.	3	THE WITNESS: I don't think I've seen anything from Johnson & Johnson, per se.
3 4			
	Q Sure.	3	anything from Johnson & Johnson, per se.
4	<ul><li>Q Sure.</li><li>A So, you know, I wouldn't be the person</li></ul>	3 4	anything from Johnson & Johnson, per se.  Is that what is that what you're
4 5	Q Sure.  A So, you know, I wouldn't be the person who prescribes chemotherapy or provides the	3 4 5	anything from Johnson & Johnson, per se.  Is that what is that what you're referring to?
4 5 6	Q Sure. A So, you know, I wouldn't be the person who prescribes chemotherapy or provides the surgery. Part of my work is as an intensive care	3 4 5 6	anything from Johnson & Johnson, per se.  Is that what is that what you're referring to?  BY MS. PARFITT:
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1	me one second. I apologize here.	1	Q But my question
2	Okay. It's your reference materials	2	MS. PARFITT: And noted.
3	reviewed and considered start on or in	3	BY MS. PARFITT:
4	Appendix B of your report.	4	Q My question to you is, sitting here
5	Do you see that?	5	today, what I need to know and if it's no,
6	A I don't see Longo and Rigler.	6	that's a fine answer. If it's yes, that's a fine
7	Q Okay. At the very top, it has	7	answer.
8	"Materials Reviewed and Considered by Gregory	8	Have you read the expert report of
9	Diette," and the second item under "Expert	9	Drs. Longo and Rigler dated November 14, 2018?
10	References" says "Expert report of William Longo	10	If you did, I'm not I'm not
11	and Mark Rigler."	11	MS. BROWN: Objection to the form. I
12	Do you see that?	12	think he answered that.
13	A Oh, I do, yeah. So I see Longo, and I'm	13	Counsel, I think what you're really
14	just	14	after is, is he relying on that to form his
15	Q Do you see Rigler? He's right after	15	opinion.
16	that. It says William	16	MS. PARFITT: Actually, I'm not. That's
17	A Oh, got you.	17	a good question, but I'm not asking that.
18	MS. BROWN: Counsel, these are reports.	18	BY MS. PARFITT:
19	I thought your question was about a deposition.	19	Q Did you read the report?
20	MS. PARFITT: That's a that's a fair	20	A So I I'm not sure if I read this one
21	objection.	21	with this particular date.
22	BY MS. PARFITT:	22	Q That's fine.
23	Q Have you read the expert report of	23	A But wait, wait. But, you know, if
24	William Longo and Mark Rigler?	24	it's on here, because that's what it reminds me
25	A So, because I see there's a date on it	25	of, I don't have a specific memory for this matter
	•		
	Page 67		Page 69
1	of November 14th, 2018	1	because I've been reading some of these things for
2	Q Correct.	2	other matters as well. So I you know, I don't
3	A I know I've seen at least a few of	3	remember whether whether I read that particular
4	Dr. Longo's reports, and I I think they're the	4	one, but if it looked like other ones that I had,
5	same over and over again. So I if I if I'm	5	I would have, you know, touched it, opened it,
6	not mistaken, I don't think I would have reread it	6	looked to see what was in there, and then not read
7	like, you know, specifically for this matter if it	7	every word of it. But I don't remember which way
8	looked the same as others. I think I probably	8	it worked.
9	just like flipped through it to see what it was	9	Q Sitting here today, are you able to tell
10	was there generally.	10	me the results of Dr. Longo and Rigler's testing
11	Q All right. So I understand your answer,	11	of Johnson & Johnson's talcum powder products as
12	is your testimony that you don't recall	12	reflected in their expert reports of November 14,
13	specifically reviewing the November 14th, 2018	13	2018?
	annest senset of Dr. Leavels and Dieles	14	MS. BROWN: Objection to the form.
14	expert report of Dr. Longo's and Rigler?		<del>=</del>
15	MS. BROWN: Objection to the form,	15	THE WITNESS: I don't remember the
15 16	MS. BROWN: Objection to the form, misstates his testimony.	15 16	THE WITNESS: I don't remember the details, but I could I could look that up and
15	MS. BROWN: Objection to the form, misstates his testimony.  MS. MILLER: So can I say something?	15	THE WITNESS: I don't remember the details, but I could I could look that up and pull pull out what I saw.
15 16 17 18	MS. BROWN: Objection to the form, misstates his testimony.  MS. MILLER: So can I say something? Because I was involved in that, I think that every	15 16 17 18	THE WITNESS: I don't remember the details, but I could I could look that up and pull pull out what I saw. BY MS. PARFITT:
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		1	
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1	marking exhibits, I'm thinking like that's not	1	wouldn't say I rely on it in the sense that it's
2	what I do. So, no so I don't know.	2	an underpinning of an opinion or something like
3	Q All right.	3	that.
4	A This particular one, I might have	4	Q All right. Do you have an understanding
5	highlighted an earlier one or or even not. And	5	then that Drs. Longo and Rigler found the presence
6	the only reason I say that is because his reports	6	of asbestos in the talcum powder products they
7	tend to have an awful lot of like sort of like	7	tested?
8	testing data in the in the back of it, and	8	MS. BROWN: Objection to the form of the
9	there's not a lot of like words, you know, to	9	question.
10	read. So there's not a lot to really highlight	10	THE WITNESS: My my understanding is
11	for me. I mean, you know what I mean? It's kind	11	they say they found it, but I don't I don't
12	of succinct in terms of like the opinion part, and	12	know the fact of whether they found it or not.
13	then there's a whole bunch of scientific stuff	13	BY MS. PARFITT:
14	that's somebody else's field.	14	Q Okay. Did from your read or not read
15	Q Understood. And I think what I'm	15	of Drs. Longo and Rigler strike that.
16	getting at is for purposes of the opinions you are	16	Did Drs. Longo and Rigler find
17	presenting to the jury in this case, are you	17	asbestiform fibers in the tests done of Johnson &
18	relying on the test results of Dr. Longo's and	18	Johnson's product, talcum powder products?
19	Rigler's that are contained in not only their	19	MS. BROWN: Objection to the form.
20	November 14th contained in their November 14th,	20	THE WITNESS: I guess I need to know
21	2018 report?	21	what we're talking about if you say "asbestiform
22	MS. BROWN: And objection.	22	fibers," because I thought your question before
23	Counsel, you said "jury." I assume you	23	was asbestos.
24	mean for purposes of this Daubert hearing, is he	24	BY MS. PARFITT:
25	relying on the Rigler and Longo report of	25	Q It was.
	Daga 71		
	Page 71		Page 73
1	November 14th, 2018.	1	_
1 2		1 2	A And are you expecting me to to say that that's two different things, or is it just
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2	November 14th, 2018. BY MS. PARFITT: Q For purposes of the opinions that you	2 3	A And are you expecting me to to say that that's two different things, or is it just another way of you trying to ask the same
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Gregory B. Diette, M.D.

	Page 74		Page 76
1	about asbestos, we're talking about a particular	1	would not alter your analysis, and I assume
2	kind of mineral that's in a particular form or	2	opinions, with regard to talcum powder products
3	habit.	3	causing ovarian cancer.
4	And so I I think when you're talking	4	A That's in my report?
5	about an asbestiform fiber, there's some	5	Q Yes.
6	redundancy there in a way, right, which is that	6	A Can we flip to that?
7	that's a description that you could apply to	7	Q Sure. Why don't you go to page 3.
8	something that other people would call asbestos.	8	And if I may, it's at the bottom,
9	BY MS. PARFITT:	9	paragraph 6.
10	Q All right. Fine. Thank you.	10	A I'm with you, yeah.
11	Has Johnson & Johnson provided you with	11	Q Okay. And it says: "To the extent
12	any testing that they performed on their product?	12	plaintiffs' expert opined that asbestos is an
13	MS. BROWN: Objection.	13	accessory mineral present in cosmetic talc that
14	BY MS. PARFITT:	14	causes ovarian cancer, this theory would not alter
15	Q Shower to Shower or Johnson's Baby	15	the analysis because the existing epidemiological
16	Powder.	16	literature regarding talc use would
17	MS. BROWN: Objection.	17	necessarily"
18	THE WITNESS: I don't think I have seen	18	MS. BROWN: You're reading it
19	anything.	19	MS. PARFITT: Beg your pardon?
20	BY MS. PARFITT:	20	MS. BROWN: You read it wrong. Perineal
21	Q Did you ever ask Johnson & Johnson to	21	talc use.
22	see any of the testing that they performed on	22	MS. PARFITT: Oh, I'm sorry. Perineal.
23	their own talcum powder products?	23	Thank you.
24	MS. BROWN: Objection. Asked and	24	BY MS. PARFITT:
25	answered.	25	Q "perineal talc use would necessarily
	2 75		5
	Page 75		Page 77
1	THE WITNESS: I have not.	1	account for the presence of any asbestos in the
2			
	BY MS. PARFITT:	2	products used in both studies."
3	Q Okay. Dr. Diette, are you aware that	2 3	products used in both studies."  Did I now read that correctly, with
3 4	Q Okay. Dr. Diette, are you aware that there are generic talcum powder products being	2 3 4	products used in both studies."  Did I now read that correctly, with counsel's correction?
3 4 5	Q Okay. Dr. Diette, are you aware that there are generic talcum powder products being sold in the marketplace today that contain an	2 3 4 5	products used in both studies."  Did I now read that correctly, with counsel's correction?  A Yeah, you're you've got it right now.
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all over the world, right. And so everything comes down to dose in any case, right. So to be concerned about it, you'd have to show that there's a sufficient dose that a person go in order to raise the risk of whatever it is the you're talking about.  A No.  Q You will not.  Q Have you made an assumption then for purposes of your opinion that Johnson's – that  Johnson & Johnson's talcum powder products do not to contain asbestos?  A I will not.  Q Have you made an assumption then for purposes of your opinion that Johnson's – that  Johnson & Johnson's talcum powder products do not to contain asbestos?  Let I recognize that there's a debate about that, and I don't have the expertise to sort through that ferbate.  Johnson's talcum powder products base to it. Are you with me?  A I am, yeah.  A I am I am product in the right of the right of the products to consumers to use it in their genital areas?  MS. BROWN: Objection. Counsel, that's an incomplete hypothetical. Is that the same tale that is in the epi?  MS. PARFITT:  MS. BROWN: Objection to the incomplete hypothetical.  MS. BROWN: Objection to the incomplete hypothetical.  THE WITNESS: So, anyway, so the needless part, I think — I'm not sure if you need that in your question or whether it changes how I would answer it. I think the general issue is whether or not there's a risk of — did you say "ovarian cancer" in your question?  MS. PARFITT:  MS. BROWN: Objection to the incomplete hypothetical.  THE WITNESS: So, anyway, so the needless part, I think the general issue is whether or not there's a risk of whether there's a danger. And from what I can tell from reading the literature, that there's not a risk of — did you say "ovarian cancer" in your question?  MS. PARFITT:  A I am, yeah.  A I am yeak.  A I fire the world, right And bout that there's a byour's talking about.  BY MS. PARFITT:  BY MS. PARFITT:  Q Please.  A If we're talking about what exists the world right now, I	age 80
Are you going to be giving an opinion in this case that Johnson & Johnson's talcum powder products contain asbestos?  A No. 5 A No. 5 A I will not. 7 A I will not. 7 A I will not. 7 B Q Have you made an assumption then for 9 purposes of your opinion that Johnson's - that 10 Johnson's A Johnson's talcum powder products do not 11 contain asbestos? 11 L - I recognize that there's a debate about that, 12 Johnson & Johnson's talcum powder products do not 12 L - I recognize that there's a debate about that, 13 Johnson's right about that debate. 15 Johnson's right about that debate. 15 Johnson's right about that debate. 15 Johnson's Johnson of Johnson's Johnson of Johnson of Johnson's Johnson of Johnson of Johnson's Johnson's Johnson's Johnson's Johnson of Johnson of Johnson of Johnson's Johnson's Johnson's Johnson's Johnson's Johnson's Johnson's Johnson of Joh	ng
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7 A I will not. 8 Q Have you made an assumption then for 9 purposes of your opinion that Johnson's that 10 Johnson & Johnson's talcum powder products do not 11 contain asbestos? 12 A I no, I haven't made that assumption. 13 I I recognize that there's a debate about that, 14 and I don't have the expertise to sort through 15 what's right about that debate. 16 Q All right. Assume that Johnson & 17 Johnson's talcum powder products contain asbestos, 18 would that place consumers that use the product in 19 needless danger? 19 meddless danger? 20 MS. BROWN: Objection. Counsel, that's 21 an incomplete hypothetical. Is that the same tale 22 that's in the epi? 23 BY MS. PARFITT: 24 Q Can you answer the question? 25 MS. BROWN: Objection to the incomplete 26 hypothetical. 27 witness. 28 MS. BROWN: Objection to the incomplete 29 hypothetical. 30 MS. BROWN: Objection to the incomplete 31 hypothetical. 41 THE WITNESS: So, anyway, so the 42 needless part, I think I'm not sure if you need 43 that in your question or whether it changes how I 44 or would answer it. I think the general issue is 45 whether or not there's a risk or whether there's a 46 danger. And from what I can tell from reading the 47 little with the desire it changes how I 48 whicher or not there's a risk or whether there's a 49 danger. And from what I can tell from reading the 40 literature, that there's not a risk of - did you 41 as would answer it. I think the general issue is 41 A Yeah, I don't see that there's a - a 42 risk of ovarian cancer* in your question? 43 A Yeah, I don't see that there's a - a 44 A Yeah, I don't see that there's a - a 45 risk of ovarian cancer from the literature. 46 Q Assume for purposes of my question that 47 Johnson & Johnson & Johnson to sell its talcum powder products has 48 asbestos in it, would it be imprudent at an out 49 responsible for Johnson & Johnson to sell ith there's an eads that we're in together, you and 40 you aware of that?  41 Johnson & Johnson, was deposed in this of the product in the product in th	that
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9 purposes of your opinion that Johnson's that 10 Johnson & Johnson's talcum powder products has asbe it. Are you with me? 11 contain asbestos? 12 A I no, I haven't made that assumption. 13 I - I recognize that there's a debate about that, 14 and I don't have the expertise to sort through 15 what's right about that debate. 16 Q All right. Assume that Johnson & 17 Johnson's talcum powder products has asbe it. Are you with me? 18 would that place consumers to use it in their 19 needless danger? 20 MS. BROWN: Objection. Counsel, that's 21 an incomplete hypothetical. Is that the same talc 22 that's in the epi? 23 BY MS. PARFITT: 24 Q Can you answer the question? 25 MS. BROWN: Objection to the incomplete 26 MS. BROWN: Objection to the incomplete 27 MS. BROWN: Object to the entire 28 hypothetical. 29 witness. 20 MS. BROWN: Objection to the incomplete 20 MS. BROWN: Objection to the incomplete 21 witness. 22 MS. BROWN: Objection to the incomplete 23 hypothetical. 24 MS. BROWN: Objection to the incomplete 25 MS. BROWN: Objection to the incomplete 26 that in your question or whether it changes how I would answer it. I think the general issue is whether or not there's a risk or whether there's a whether or not there's a risk or whether there's a label and it is provided and provided products to consumers to use it in their genital areas?  MS. BROWN: Objection to the incomplete of question, Counsel. Are you divorcing your hypothetical from the epidemiology he has and is here to talk about?  MS. PARFITT: Q Counsel. Counsel. If he understood the last question, it's the sam the understood the last question, or sursel, if he understant he understood the last question, or sursel, if he understant he understood the last question, or sursel, if he understant he understood the last question, or	ınson &
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16 Q All right. Assume that Johnson & 16 17 Johnson's talcum powder products contain asbestos, 17 18 would that place consumers that use the product in 19 19 needless danger? 19 20 MS. BROWN: Objection. Counsel, that's 20 21 an incomplete hypothetical. Is that the same talc 21 that's in the epi? 22 that's in the epi? 22 that's in the epi? 22 that's in the epi? 23 24 Q Can you answer the question? 24 MS. BROWN: I object to the entire 25 MS. PARFITT: 23 Thank you. 24 25 MS. PARFITT: 24 Q Can you answer the question? 25 MS. BROWN: Objection to the incomplete 25 MS. BROWN: Object to the entire 26 of questioning. 27 28 MS. BROWN: Object to the incomplete 27 29 hypothetical. 3 A If we're talking about what exists 29 that in your question or whether it changes how I 29 danger. And from what I can tell from reading the 29 Q Susan Nicholson. 20 Q Susan Nicholson. 20 Q Susan Nicholson. 21 PY MS. PARFITT: 22 PY MS. PARFITT: 23 PY MS. PARFITT: 24 PY MS. PARFITT: 25 PY MS. PARFITT: 26 PY MS. PARFITT: 27 PY MS. PARFITT: 28 PY MS. PARFITT: 29 PY MS. PARFITT: 20 PY MS. PARFITT: 20 PY MS. PARFITT: 20 PY MS. PARFITT: 20 PY MS. PARFITT: 21 PY MS. PARFITT: 22 PY MS. PARFITT: 21 PY MS. PARFITT	
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reasonable for Johnson & Johnson to sell that 19 you aware of that?	
21 MS. BROWN: Objection to the incomplete 21 Q Okay. And the deposition that wa	was taken
hypothetical. 22 of Dr. Nicholson was a deposition that was	
23 THE WITNESS: So I think, you know, it 23 wherein she we call it a 30(b)(6). That	
24 isn't a yes or no, right? I mean, because it's 24 she represents the voice of the company the	
25 if you're talking about asbestos, there's asbestos 25 works for. Understand?	1111 SHC
works for. Oligorstatic:	

	Page 82		Page 84
1	MS. BROWN: Objection to the form of the	1	Q Okay. At the top, if I may, it says
2	question.	2	line 2: "Well" and I'll represent to you that
3	THE WITNESS: I understand what you	3	I was one of the attorneys that took
4	said. I don't know what I if I understand what	4	Dr. Nicholson's deposition.
5	that means.	5	The question is: "Well, if your
6	MS. PARFITT: Okay. All right. Let me	6	products contain asbestos, would you agree with me
7	have marked as Exhibit I believe it's	7	that that impacts the safety of the product?"
8	Exhibit No. 6 that we're on.	8	Answer: "Absolutely, yes."
9	(Diette Exhibit No. 6 was marked	9	Next question: "Would you agree that
10	for identification.)	10	Johnson & Johnson has a zero tolerance policy with
11	MS. BROWN: And, Counsel, if you're	11	regard to having asbestos in their talcum powder
12	going to ask him questions about Dr. Nicholson's	12	products?"
13	deposition that he has not reviewed, we need to at	13	The answer: "Yeah, that is correct."
14	least have a full copy of the deposition here.	14	Next question: "In fact, as a
15	Thanks.	15	representative of the company, it's your position
16	MS. PARFITT: I believe you have	16	that your Johnson & Johnson's talcum powder
17	MS. BROWN: And you should take as long	17	products should not contain asbestos; is that
18	as you need to review it to answer any questions	18	correct?"
19	counsel might have.	19	"That's correct that is correct."
20	MS. PARFITT: Okay. And, Counsel, I'll	20	Next question: "And you would agree
21	get you that I don't have a copy	21	with me that if your talcum powder products had
22	MS. BROWN: We have I mean your	22	asbestos in them, it would place the consumers
23	colleague just	23	that use your product in needless danger,
24	MS. PARFITT: We have just one. I'm	24	correct?"
25	just saying we just have one. I don't have one	25	"It could, yes."
	Page 83		Page 85
1	for you.	1	Next question on page 48 of that same
2	MS. BROWN: As long as the doctor has	2	deposition
3	time to review it you know he hasn't seen this	3	MS. BROWN: Counsel, I'm sorry, but your
4	before. If you're going to ask him questions	4	pages are not matching up to what we've been
5	about it, he needs to read it.	5	handed. Can you just direct us and we're in
6	MS. PARFITT: Just one.	6	the snippet you gave us, I can't find this.
7	BY MS. PARFITT:	7	THE WITNESS: I don't have 48. Mine
8	Q Dr. Nich or Dr. Diette, let me	8	goes to 41.
9	direct your attention to page 37.	9	MS. BROWN: Yeah, mine says 37, 37, 37.
10	A Okay.	10	THE WITNESS: Maybe here in the whole
11	Q And specifically line 2, and let me read	11	thing?
12	it. We'll put it up on the ELMO.	12	MR. HEASLIP: And mine is 46 through 53.
13	MS. BROWN: Counsel, while you're doing	13	MS. PARFITT: Okay.
14	that, I'm going to object to taking one page out	14	MS. BROWN: This is not what you're
	of Dr. Nicholson's deposition that the doctor has	15	reading, so it's impossible to follow.
15		T. Contract of the Contract of	
15 16	not reviewed and asking questions out of context.	16	Were you able to follow that, Doctor?
		16 17	Were you able to follow that, Doctor?  MS. PARFITT: We have it on the
16	not reviewed and asking questions out of context.		•
16 17	not reviewed and asking questions out of context.  And if he needs to read the whole deposition to	17	MS. PARFITT: We have it on the
16 17 18	not reviewed and asking questions out of context.  And if he needs to read the whole deposition to answer your question, he will need to do that.	17 18	MS. PARFITT: We have it on the overhead. I think
16 17 18 19	not reviewed and asking questions out of context.  And if he needs to read the whole deposition to answer your question, he will need to do that.  MS. PARFITT: Counsel, please not	17 18 19	MS. PARFITT: We have it on the overhead. I think MR. ROSEN: I go to I go to 41.
16 17 18 19 20	not reviewed and asking questions out of context.  And if he needs to read the whole deposition to answer your question, he will need to do that.  MS. PARFITT: Counsel, please not let's not coach.  MS. BROWN: And I'm objecting on the	17 18 19 20	MS. PARFITT: We have it on the overhead. I think MR. ROSEN: I go to I go to 41. MS. BROWN: Yeah, well, he needs to have
16 17 18 19 20 21	not reviewed and asking questions out of context.  And if he needs to read the whole deposition to answer your question, he will need to do that.  MS. PARFITT: Counsel, please not let's not coach.	17 18 19 20 21	MS. PARFITT: We have it on the overhead. I think MR. ROSEN: I go to I go to 41. MS. BROWN: Yeah, well, he needs to have it in front of him. We don't have a copy.
16 17 18 19 20 21	not reviewed and asking questions out of context.  And if he needs to read the whole deposition to answer your question, he will need to do that.  MS. PARFITT: Counsel, please not let's not coach.  MS. BROWN: And I'm objecting on the record to the improper questioning with snippets	17 18 19 20 21 22	MS. PARFITT: We have it on the overhead. I think  MR. ROSEN: I go to I go to 41.  MS. BROWN: Yeah, well, he needs to have it in front of him. We don't have a copy.  MS. PARFITT: Well, let's do this. I

	Page 86		Page 88
1	questions?	1	Did I read all that correctly?
2	MS. BROWN: But, Counsel, that's not	2	A You did.
3	even a transcript. What is that?	3	Q All right. Do you so you disagree
4	MS. PARFITT: It's	4	with Dr. Nicholson; is that correct?
5	MS. MILLER: How are you going to mark	5	MS. BROWN: Objection to the form.
6	that as an exhibit?	6	MR. LOCKE: Objection.
7	MS. PARFITT: I'm going to put an	7	MS. BROWN: Misstates his testimony.
8	exhibit sticker on it, and I'm going to put it in	8	THE WITNESS: I don't I don't agree
9	as representative pages from the Nicholson	9	or disagree. I mean, I I honestly don't know
10	deposition.	10	who she is other than what you just said. But
11	MS. BROWN: Can he find it in the large	11	but it sounds like she's articulating a policy for
12	copy?	12	the company, which I think is her right her
13	MR. ROSEN: Would you mind passing	13	right to do that and to express those opinions.
14	back Exhibit 6 that we handed	14	BY MS. PARFITT:
15	THE WITNESS: Oh. This is all of your	15	Q Okay. All right.
16	36's. That's a whole bundle of the same thing.	16	Okay. Now, counsel provided for us in
17	But I would like to get the 36-page	17	advance of this deposition a copy of your CV. So
18	back	18	let me
19	MS. PARFITT: Sure.	19	THE WITNESS: Would it would it be a
20	THE WITNESS: if we're going to talk	20	good time just to refill coffee? Is that okay?
21	about it.	21	MS. PARFITT: Sure. And I should have
22	MS. PARFITT: Absolutely. I want you to	22	said that. Any time you need a break
23	have actually 37, and you need here we go.	23	THE WITNESS: No, I know.
24	MS. BROWN: This is the complete set?	24	MS. PARFITT: you holler.
25	MS. PARFITT: Yes, I'm assuming.	25	THE WITNESS: Thank you. I appreciate
	Mo. 11114 111. 100, 111 usouming.		, , , , , , , , , , , , , , , , , , ,
	Page 87		Page 89
1	MS. BROWN: You have that in front of	1	that.
2	you?	2	MS. PARFITT: You're very welcome.
3	THE WITNESS: I do.	3	THE VIDEOGRAPHER: The time is 10:07
4	BY MS. PARFITT:	4	p.m. We're going off the record.
5	Q And, Dr. Diette, if you have any trouble	5	(Recess.)
6	reading any of that or you can also look up on	6	THE VIDEOGRAPHER: The time is
7	the ELMO that's being displayed.		
_		7	10:20 a.m., and we're back on the record.
8	MS. BROWN: Thank you.	7 8	10:20 a.m., and we're back on the record. BY MS. PARFITT:
9			
	MS. BROWN: Thank you.	8	BY MS. PARFITT:
9	MS. BROWN: Thank you. MS. PARFITT: Okay. Yeah, sorry.	8 9	BY MS. PARFITT:  Q Dr. Diette, are you still
9 10	MS. BROWN: Thank you.  MS. PARFITT: Okay. Yeah, sorry. BY MS. PARFITT:	8 9 10	BY MS. PARFITT:  Q Dr. Diette, are you still THE VIDEOGRAPHER: Microphone, Counsel.
9 10 11	MS. BROWN: Thank you. MS. PARFITT: Okay. Yeah, sorry. BY MS. PARFITT: Q Again, page 48, line 14.	8 9 10 11	BY MS. PARFITT:  Q Dr. Diette, are you still  THE VIDEOGRAPHER: Microphone, Counsel. BY MS. PARFITT:
9 10 11 12	MS. BROWN: Thank you. MS. PARFITT: Okay. Yeah, sorry. BY MS. PARFITT: Q Again, page 48, line 14. Do you have that there, Doctor, in front	8 9 10 11 12	BY MS. PARFITT:  Q Dr. Diette, are you still  THE VIDEOGRAPHER: Microphone, Counsel. BY MS. PARFITT:  Q Are you good?
9 10 11 12 13	MS. BROWN: Thank you. MS. PARFITT: Okay. Yeah, sorry. BY MS. PARFITT: Q Again, page 48, line 14. Do you have that there, Doctor, in front of you?	8 9 10 11 12 13	BY MS. PARFITT:  Q Dr. Diette, are you still  THE VIDEOGRAPHER: Microphone, Counsel. BY MS. PARFITT:  Q Are you good?  A All set. Thank you.
9 10 11 12 13 14	MS. BROWN: Thank you. MS. PARFITT: Okay. Yeah, sorry. BY MS. PARFITT: Q Again, page 48, line 14. Do you have that there, Doctor, in front of you? A I do.	8 9 10 11 12 13 14	BY MS. PARFITT:  Q Dr. Diette, are you still THE VIDEOGRAPHER: Microphone, Counsel. BY MS. PARFITT: Q Are you good? A All set. Thank you. Q All right. Dr. Diette, if asbestos was
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9 10 11 12 13 14 15	MS. BROWN: Thank you. MS. PARFITT: Okay. Yeah, sorry. BY MS. PARFITT: Q Again, page 48, line 14. Do you have that there, Doctor, in front of you? A I do. Q Okay. "Q. You would agree, Dr. Nicholson, if	8 9 10 11 12 13 14 15	BY MS. PARFITT:  Q Dr. Diette, are you still THE VIDEOGRAPHER: Microphone, Counsel. BY MS. PARFITT: Q Are you good? A All set. Thank you. Q All right. Dr. Diette, if asbestos was found to be in talcum powder products strike that.
9 10 11 12 13 14 15 16	MS. BROWN: Thank you.  MS. PARFITT: Okay. Yeah, sorry.  BY MS. PARFITT:  Q Again, page 48, line 14.  Do you have that there, Doctor, in front of you?  A I do.  Q Okay.  "Q. You would agree, Dr. Nicholson, if Johnson & Johnson's Baby Powder indeed had	8 9 10 11 12 13 14 15 16 17	BY MS. PARFITT:  Q Dr. Diette, are you still THE VIDEOGRAPHER: Microphone, Counsel. BY MS. PARFITT: Q Are you good? A All set. Thank you. Q All right. Dr. Diette, if asbestos was found to be in talcum powder products strike that. Would the presence of asbestos in talcum
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	Page 90		Page 92
1	MS. BROWN: Objection to the form of the	1	papers that have been either accepted or published
2	question.	2	since then. There's probably some talks and
3	THE WITNESS: You would have to qualify	3	things. The the grant award section I'm sure
4	it, right, because I if you're talking about	4	needs updating.
5	like even like, you know, one fiber or	5	Q Okay. It looks, on the far right of
6	something would be quite different than if there's	6	that CV, that it's got a June 2017 date; is that
7	a sufficient amount in order to to cause a	7	correct?
8	disease, right. So it it always comes down to	8	A It is.
9	dose in terms of what you're talking about.	9	Q All right. Has there been a curriculum
10	So it's all by itself, I don't think	10	vitae prepared by you since June of 2017?
11	that that question is answerable.	11	A No.
12	BY MS. PARFITT:	12	Q All right. Where would I get these
13	Q Can one fiber of asbestos alone cause	13	additional articles and speeches? Do you have
14	cancer?	14	them in a contained in one particular place?
15	MS. BROWN: Objection to the form.	15	A No. Where where you could get the
16	THE WITNESS: It's it's so impossible	16	articles would be on PubMed, and if you just did a
17	to think that it would, because we all have	17	PubMed search with my name, you would find them
18	asbestos in our lungs, and there's a background	18	all.
19	amount of asbestos in the world that if one fiber	19	For speeches, I don't actually have a
20	could do it, I think we would all have cancer. So	20	repository, so it's going to take me some work to
21	I I think somebody could say that, but I don't	21	actually sort of populate that part of the CV.
22	think it would be true.	22	Q Are you do you have any intention of
23	BY MS. PARFITT:	23	updating your CV?
24	Q You certainly don't think it's true; is	24	A Yes. Can I give you an extra sentence
25	that correct?	25	or two?
	Page 91		Page 93
1	Page 91  A Oh, for sure, yeah.	1	Page 93 Q Sure.
1 2		1 2	
	A Oh, for sure, yeah.		Q Sure.
2	<ul><li>A Oh, for sure, yeah.</li><li>Q Okay. Let me mark at this time a</li></ul>	2	<ul><li>Q Sure.</li><li>A Okay. So I sure want to. The stakes</li><li>are low for me at this point. This is our</li></ul>
2	A Oh, for sure, yeah.  Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll	2 3	<ul><li>Q Sure.</li><li>A Okay. So I sure want to. The stakes</li></ul>
2 3 4	A Oh, for sure, yeah.  Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll have it marked as exhibit Exhibit 7.	2 3 4	Q Sure. A Okay. So I sure want to. The stakes are low for me at this point. This is our Department of Medicine format CV, which we use for
2 3 4 5	A Oh, for sure, yeah.  Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll have it marked as exhibit Exhibit 7.  (Diette Exhibit No. 7 was marked	2 3 4 5	Q Sure. A Okay. So I sure want to. The stakes are low for me at this point. This is our Department of Medicine format CV, which we use for promotion purposes, for the most part. I've been
2 3 4 5 6	A Oh, for sure, yeah.  Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll have it marked as exhibit Exhibit 7.  (Diette Exhibit No. 7 was marked for identification.) BY MS. PARFITT:	2 3 4 5 6	Q Sure. A Okay. So I sure want to. The stakes are low for me at this point. This is our Department of Medicine format CV, which we use for promotion purposes, for the most part. I've been promoted to professor, which there's no other rank
2 3 4 5 6 7	A Oh, for sure, yeah.  Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll have it marked as exhibit Exhibit 7.  (Diette Exhibit No. 7 was marked for identification.)	2 3 4 5 6 7	Q Sure. A Okay. So I sure want to. The stakes are low for me at this point. This is our Department of Medicine format CV, which we use for promotion purposes, for the most part. I've been promoted to professor, which there's no other rank to get promoted to. And so it's not really that
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A Oh, for sure, yeah. Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll have it marked as exhibit Exhibit 7. (Diette Exhibit No. 7 was marked for identification.)  BY MS. PARFITT: Q Do you have that in front of you? A I do. Q Okay. Who prepared that curriculum vitae? A Well, not one person. This is an iterative exercise over time. So it's I mean, me in the sense, although not as the person, you know, typing the words, but it's you know, it's my my information on here. And I've had	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q Sure. A Okay. So I sure want to. The stakes are low for me at this point. This is our Department of Medicine format CV, which we use for promotion purposes, for the most part. I've been promoted to professor, which there's no other rank to get promoted to. And so it's not really that urgent for me to to change that.  Then on top of that, my administrative assistant went out on maternity leave, and then I didn't want to swamp her with this when she came back.  Q That was nice. A And literally just last week, she took a new job, a better job but in a different place. So long answer, yeah, I want to, but it's not going to happen really soon.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A Oh, for sure, yeah. Q Okay. Let me mark at this time a copy a copy of your curriculum vitae, and we'll have it marked as exhibit Exhibit 7. (Diette Exhibit No. 7 was marked for identification.)  BY MS. PARFITT: Q Do you have that in front of you? A I do. Q Okay. Who prepared that curriculum vitae? A Well, not one person. This is an iterative exercise over time. So it's I mean, me in the sense, although not as the person, you know, typing the words, but it's you know, it's my my information on here. And I've had different administrative assistants who have who have helped to sort of shape it. Q Is it current? A No. Q It's not? A It's not.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Sure. A Okay. So I sure want to. The stakes are low for me at this point. This is our Department of Medicine format CV, which we use for promotion purposes, for the most part. I've been promoted to professor, which there's no other rank to get promoted to. And so it's not really that urgent for me to to change that.  Then on top of that, my administrative assistant went out on maternity leave, and then I didn't want to swamp her with this when she came back.  Q That was nice. A And literally just last week, she took a new job, a better job but in a different place. So long answer, yeah, I want to, but it's not going to happen really soon. Q Okay. So your current academic appointment at Johns Hopkins University, is that a professor of medicine, is that correct, Division of Pulmonary and Critical Care?

1 A And sleep, yeah. 2 Q All right. Are you still within the 3 Department of Fipidemiology? 4 A Yes. 5 Q All right. Are you still an associate professor of medicine in epi and environmental health? 5 Q All right. Are you still an associate professor of medicine in epi and environmental health? 6 A No, that's a typo somewhere. I don't know where you saw that, but - od, probably in my report. But, no, l'm - the professor fabel carries across all the - the different entities. 12 Q So you're no longer an associate professor. 13 professor. 14 A Right. Professor of whatever it is that professor fabel carries across all the - the different entities. 15 Pm a professor of. 16 Q All right. Your board certification is in purpolation of the professor of professor of whatever it is that in the professor of professor. 16 Q All right. Your board certification is in purpolation of the professor of professor of whatever it is that in the professor of professor of professor of whatever it is that in the professor. 16 Q All right. Now that member of the American in the professor of whatever it is that it is correct. 15 Pm a professor of whatever it is that it is correct. 20 A No. 21 College of Epidemiology, correct? 22 A No. 23 Q Your undergraduate degree was in engage of Epidemiology, correct? 24 English? 25 A English and economics.  26 A So Bay Shape and professor of whatever it is that correct? 27 A Well, it was in epidemiology. 28 A Well, it was in epidemiology. 39 A Well, it was in epidemiology. 40 Q Okay. Let me s		Page 94		Page 96
2 Q All right. So if someone were going on 3 Department of Epidemiology? 4 A Yes. 5 Q All right. Are you still an associate 5 professor of medicine in epi and environmental 6 health? 8 A No, that's a typo somewhere. I don't 9 know where you saw that, but oh, probably in my 10 report. But, no, f.m the professor label 11 carries across all the the different entities. 12 Q So you're no longer an associate 13 professor. 14 A Right. Professor of whatever it is that 15 I'm a professor of. 16 Q All right. Your board certification is 17 in pulmonary and critical care? 18 A It's in internal medicine and pulmonary 19 medicine. 20 Q You're not a member of the American 21 College of Epidemiology, correct? 22 A No. 23 Q Your undergraduate degree was in 24 English? 25 A English and economics.  Page 95 1 Q Okay. And then post-medicia school, you 27 received a MHS in public health, and that's not what mine 28 was called. 29 Q Okay. Let me show you what we'll have 29 marked as the Johns Hopkins Medicine website as 20 kan a repidemiology. 20 Gokay. Let me show you what we'll have 21 mass a repidemiology. 22 mass a repidemiology. 23 Q Okay. Let me show you what we'll have 24 Q Okay. Let me show you what we'll have 25 mass a repidemiology. 26 G All right. Do you have that in front of 27 Q All right. Do you have that in front of 28 you? 29 You're not a member of the American 20 Q Okay. Let me show you what we'll have 21 mass a repidemiology. 22 medicine. 23 Q Okay. Let me show you what we'll have 24 Q Okay. Let me show you what we'll have 25 mass a flow in the professor and find a 26 degree in public health, and that's not what mine 27 mass a repidemiology of a received a Branchia short was called. 28 Q Okay. Let me show you what we'll have 29 mass a flow in the professor and reproduced and all kinds of things, but I don'tI 29 don't know what the format is for this. Like I don't know what the format is for this. Like I don't know what the format is for this. I ske I 29 Q All right. Do you have that in front of 29 Q A	1	A And sleep, yeah.	1	hospital as well.
Department of Epidemiology?  A Yes.  Q All right. Are you still an associate professor of medicine in epi and environmental professor of medicine carries across all the — the different entities.  Q All right. Is — it reads: "Expertise: Q All right. Is — it reads: "Expertise: Q All right. Is — it reads: "Expertise: Q C(OPP), pulmonary" — excuse me — "pulmonary disease, and critical care medicine, pulmonary of disease, and critical care medicine."  A Right. Professor of whatever it is that 14 A It is correct.  A Right. Professor of whatever it is that 15 Ima professor of whatever it is that 16 Ima professor of whatever it is that 17 in pulmonary and critical care?  A If in infermal medicine and pulmonary medicine.  Q You're not a member of the American College of Epidemiology, correct?  A No.  Q Your undergraduate degree was in English?  A English and economics.  Page 95  Page 95  1 Q Okay. And then post-medical school, you received a MHS in public health; is that correct?  A Well, it was in epidemiology.  A We	2		2	
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5 sec. And look over to the far right, and it has 6 professor of medicine in epi and environmental 7 health? 8 A No, that's a typo somewhere. I don't 8 know where you saw that, but oh, probably in my 10 report. But, no, I'm the professor label 11 carries across all the the different entities. 12 Q So you're no longer an associate 13 professor. 14 A Right. Professor of whatever it is that 15 I'm a professor of. 16 Q All right. Your board certification is 16 in pulmonary and critical care? 17 A I is correct. 18 A I's in internal medicine and pulmonary 18 medicine. 20 Q You're not a member of the American 21 College of Epidemiology, correct? 22 A No. 23 Q Your undergraduate degree was in 24 English and economics. 25 Page 95 26 A English and economics. 27 Q Okay. And then post-medical school, you received a MIRS in public health, is that correct? 2 A I only just say that because there is a degree in public health, is that correct? 2 A I only just say that because there is a degree in public health, and that's not what mine was called. 3 Q Okay. Let me show you what we'll have marked as the Johns Hopkins Medicine website as 2 MS. BROWN: 8 3 Page 97 4 Q Okay. Let me show you what we'll have marked as the Johns Hopkins Medicine website as 3 MS. BROWN: 8 4 (Diette Eshibit No. 8 was marked for identification.) 5 Page 97 5 Q All right. Now, this is for the Johns 6 Q Okal Iright. Now, this is for the Johns 7 Q All right. Now, this is for the Johns 8 Professor of whatever it is that to orrect or medical enterty? 9 A I do. 9 Q All right. Now, this is for the Johns 10 Q All right. Now, this is for the Johns 11 Hopkins Medical School, is that correct, or medical enterty? 12 Most Row Wash and that's not what mine was called. 13 Page 97 14 (Diette Eshibit No. 8 was marked for identification.) 15 page 97 16 page 97 17 page 97 18 page 97 19 A I do. 9 All right. Now, this is for the Johns 10 Q All right. Now, this is for the Johns 11 page 10 pa	4		4	
6 professor of medicine in epi and environmental 6 health? 7 health? 8 A No, that's a typo somewhere. I don't 8 A I do. 9 A II right. Is — it reads: "Expertise: Asthma, chronic obstructive pulmonary disease. 10 (COPD), pulmonary: — excuse me — "pulmonary disease. 11 disease, and critical care medicine, pulmonary medicine." 12 Q So you're no longer an associate 12 disease, and critical care medicine, pulmonary medicine." 13 professor. 14 A Right. Professor of whatever it is that 14 Is in internal medicine and pulmonary and critical care? 15 Is that correct? 16 Q All right. Your board certification is 16 to add with regard to your expertise? 17 M.S. BROWN: Objection to the form of the question. 18 question. 18 question. 19 THE WITNESS: So I honestly don't know what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is. I mean, I don't doubt that it cornes what this is a broader label where is a degree in public health; is that correct? 2 doctor. 2 doubt. 2 doubt and find a secure of the public health; is that cornect? 3 doctor. 4 doctor. 4 doctor. 4 doctor. 4 doctor. 4 doctor. 5 do Ryay. 6 degree in public health; is that cornect? 1 doctor. 5 doctor. 5 do Ryay. 6 degree in public health; is that cornect? 1 doctor. 5 do Ryay. 6 degree in public health; is that cornect? 1 doctor. 5 doctor. 5 doctor. 6 doctor. 6 doctor. 6 doctor. 6 doctor. 7	5	Q All right. Are you still an associate	5	
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11 carries across all the the different entities. 12 Q So you're no longer an associate 13 professor. 14 A Right. Professor of whatever it is that 15 I'm a professor of. 16 Q All right. Your board certification is 17 in pulmonary and critical care? 18 A It's in internal medicine and pulmonary 19 medicine. 19 medicine. 10 Q You're not a member of the American 11 College of Epidemiology, correct? 12 A No. 12 A English and economics. 19 Page 95 10 Q Okay. 11 Q Okay. 12 A English and economics. 19 Page 95 11 Q Okay. And then post-medical school, you received a MHS in public health; is that correct? 12 A Noll it was in epidemiology. 13 A Well, it was in epidemiology. 14 Q Okay. 15 A I only just say that because there is a degree in public health, and that's not what mine was called. 18 Q Okay. Let me show you what we'll have marked as the Johns Hopkins Medicine website as 10 MS. PARFITT: 11 MS. BROWN: 8. 12 BY MS. PARFITT: 13 Q - Exhibit 8? 14 (Diette Exhibit No. 8 was marked for identification.) 15 Green Hopkins, we marked for identification. 16 BY MS. PARFITT: 17 Q All right. Now, this is for the Johns 18 Is that correct? 18 A It is correct. 19 A I don't know what the purpose of the and with regard to your expertise? 19 MS. BROWN: 8. 10 G Nay. BROWN: Objection to the form of the question. 11 THE WITNESS: So I honestly don't know what this is. I mean, I don't doubt that it comes from Hopkins, but it's not something I look at. 10 A English and economics. 11 THE WITNESS: So I honestly don't know what the bottom, it says 12 a Go Nay. 12 BY MS. PARFITT: 13 Q - Exhibit 8? 14 (Diette Exhibit No. 8 was marked for identification.) 15 Green Hopkins Medicine, "which is obroader label" 16 BY MS. PARFITT: 17 Q All right. Now, this is for the Johns 18 A I'm and the correct!? 19 A I do. 20 Q All right. Now, this is for the Johns 21 Hopkins Medicine, "which is a broader label" 22 Wonder and whit is a medicine. 23 A So I don't know. You know, the top says 24 "Johns Hopkins Medicine, which is a broader label" 24 "Johns Hopkin	10		10	
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15    Pm a professor of.		-	14	
16 Q All right. Your board certification is in pulmonary and critical care? 18 A It's in internal medicine and pulmonary 19 medicine. 19 THE WITNESS: So I honestly don't know what this is. I mean, I don't doubt that it comes from Hopkins, but it's not something I look at. 20 Q You're not a member of the American 21 College of Epidemiology, correct? 22 A No. 23 Q Your undergraduate degree was in 24 English? 25 A English and economics.  Page 95  1 Q Okay. And then post-medical school, you received a MHS in public health; is that correct? 2 A Well, it was in epidemiology. 3 A Well, it was in epidemiology. 4 Q Okay. 4 Q Okay. 5 A I only just say that because there is a degree in public health, and than's not what mine 7 was called. 8 Q Okay. Let me show you what well have marked as the Johns Hopkins Medicine website as marked as the Johns Hopkins Medicine website as for identification.) 10 MS. PARFITT: 11 MS. BROWN: 8. 12 BY MS. PARFITT: 13 Q - Exhibit 8? 14 (Diette Exhibit No. 8 was marked for identification.) 15 BY MS. PARFITT: 16 BY MS. PARFITT: 17 Q All right. Do you have that in front of you? 18 you? 19 A I do. 20 Q All right. Now, this is for the Johns 21 Hopkins Medicine, "which is a broader label of the form of the question. 22 THE WITNESS: So I honestly don't know what the purpose of this is. 23 D Wast this is. I mean, I don't know what the form Hopkins Medicine, "which is a broader label to don't what this pust in the store of the form of the question. 24 The WITNESS: So I honestly don't know what the purpose of this is. 25 Page 95  Page 95  Page 97  1 "Request an appointment." So this looks like some kind of place that somebody could go and find a call-in number to get an appointment for for a doctor. 24 doctor. 25 D Okay. 26 D Okay. 27 C Okay. 28 D Okay. 29 Okay. 30 A I flyou well, no, just one second. 31 A Well, it was in epidemiology. 32 C Okay. 33 A Farguest an appointment." So this looks like some kind of place that somebody could go and find a call-in number to get an appointment for for a				
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17 Q All right. Do you have that in front of 18 you? 19 A I do. 20 Q All right. Now, this is for the Johns 21 Hopkins Medical School; is that correct, or 22 medical center? 23 A So I don't know. You know, the top says 24 "Johns Hopkins Medicine," which is a broader label 26 obstructive pulmonary disease, asthma." 27 Did I read that correctly? 28 A You did. 29 Q Does that accurately reflect your 20 current research interests? 21 MS. BROWN: Objection. Form. 22 MS. BROWN: Objection. Form. 23 THE WITNESS: Well, it's some, but it's 24 so incomplete. You know, it's obviously just a	13 14	Q Exhibit 8? (Diette Exhibit No. 8 was marked	13 14	Q All right. The second line says: "Research interests," and it states:
18you?18Did I read that correctly?19A I do.19A You did.20Q All right. Now, this is for the Johns20Q Does that accurately reflect your21Hopkins Medical School; is that correct, or21current research interests?22medical center?22MS. BROWN: Objection. Form.23A So I don't know. You know, the top says23THE WITNESS: Well, it's some, but it's24"Johns Hopkins Medicine," which is a broader label24so incomplete. You know, it's obviously just a	13 14 15	<ul><li>Q Exhibit 8?</li><li>(Diette Exhibit No. 8 was marked for identification.)</li></ul>	13 14 15	Q All right. The second line says: "Research interests," and it states: "Environmental impacts on lung disease,
19 A I do. 20 Q All right. Now, this is for the Johns 21 Hopkins Medical School; is that correct, or 22 medical center? 23 A So I don't know. You know, the top says 24 "Johns Hopkins Medicine," which is a broader label 29 A You did. 20 Q Does that accurately reflect your 21 current research interests? 22 MS. BROWN: Objection. Form. 23 THE WITNESS: Well, it's some, but it's 24 so incomplete. You know, it's obviously just a	13 14 15 16	<ul><li>Q Exhibit 8?</li><li>(Diette Exhibit No. 8 was marked for identification.)</li><li>BY MS. PARFITT:</li></ul>	13 14 15 16	Q All right. The second line says: "Research interests," and it states: "Environmental impacts on lung disease, epidemiology of airway disease and chronic
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	Page 98		Page 100
1	this on this page.	1	it to see if it's accurate or not, but there's
2	BY MS. PARFITT:	2	there's certainly more about me than just those
3	Q Okay. Well, I will represent to you	3	couple of
4	that if one chose to go on the Johns Hopkins	4	Q Okay. Well, you know, that's a good
5	Medicine website, this is how they hold you out to	5	point, and I missed that. So thank you for
6	the to the world, so to speak.	6	bringing that to our attention.
7	MS. BROWN: Objection to the speech. Is	7	Let's look at that sec second page
8	there a question?	8	of the website for Johns Hopkins Medical Center.
9	THE WITNESS: So	9	MR. TISI: Counsel, that is Exhibit 8.
10	MS. PARFITT: Counsel	10	MS. PARFITT: And it is Exhibit 8.
11	MS. BROWN: There's no question.	11	Thank you.
12	MS. PARFITT: please.	12	Okay. Let's put that up there.
13	MS. BROWN: Is there a question?	13	BY MS. PARFITT:
14	MS. PARFITT: Yes.	14	Q And there's a category that says
15	MS. BROWN: What is it?	15	"Background"; is that correct?
	BY MS. PARFITT:	16	A It is.
16		17	
17 18	Q Is this how is this information correct, Dr. Diette?	18	Q All right. Now, it states: "Dr. Gregory Diette is a professor of medicine at
19	A Oh, the information is correct.	19 20	the Johns Hopkins University School of Medicine.
20	Q Okay.		He holds a joint appointment in the Department of
21	A It's very incomplete.	21	Epidemiology in the Johns Hopkins Bloomberg School
22	Q Okay. Let me show you now what we'll	22	of Public Health." Hashtag, "His areas of
23	have marked as Exhibit 9.	23	clinical expertise include asthma and obstructive
24	(Diette Exhibit No. 9 was marked	24	lung disease."
25	for identification.)	25	Did I read that correctly?
	Page 99		Page 101
	_		rage 101
1	THE WITNESS: Can I just just	1	A You did.
1 2		1 2	
	THE WITNESS: Can I just just		A You did.
2	THE WITNESS: Can I just just clarify?	2	A You did. Q Okay. Is that correct?
2 3	THE WITNESS: Can I just just clarify? BY MS. PARFITT:	2 3	<ul><li>A You did.</li><li>Q Okay. Is that correct?</li><li>A That that it includes those two</li></ul>
2 3 4	THE WITNESS: Can I just just clarify? BY MS. PARFITT: Q There's no question pending right now.	2 3 4	A You did. Q Okay. Is that correct? A That that it includes those two diseases?
2 3 4 5	THE WITNESS: Can I just just clarify? BY MS. PARFITT: Q There's no question pending right now. A I want to clarify my last	2 3 4 5	A You did. Q Okay. Is that correct? A That that it includes those two diseases? Q Yes.
2 3 4 5 6	THE WITNESS: Can I just just clarify? BY MS. PARFITT: Q There's no question pending right now. A I want to clarify my last MS. BROWN: But if you want	2 3 4 5 6	A You did. Q Okay. Is that correct? A That that it includes those two diseases? Q Yes. A It does include that.
2 3 4 5 6 7	THE WITNESS: Can I just just clarify? BY MS. PARFITT: Q There's no question pending right now. A I want to clarify my last MS. BROWN: But if you want BY MS. PARFITT:	2 3 4 5 6 7	A You did. Q Okay. Is that correct? A That that it includes those two diseases? Q Yes. A It does include that. Q Okay. And the third paragraph reads:
2 3 4 5 6 7 8	THE WITNESS: Can I just just clarify? BY MS. PARFITT: Q There's no question pending right now. A I want to clarify my last MS. BROWN: But if you want BY MS. PARFITT: Q Your counsel will have a chance to to	2 3 4 5 6 7 8	A You did. Q Okay. Is that correct? A That that it includes those two diseases? Q Yes. A It does include that. Q Okay. And the third paragraph reads: "His research interests include environmental
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26 (Pages 98 to 101)

	Page 102		Page 104
1	Health, this is the type of information they would	1	patients who come to you are experiencing?
2	receive, Dr. Diette.	2	MS. BROWN: Objection to the form.
3	Look down at the "Overview." Do you see	3	THE WITNESS: And I'll do my best, and
4	that?	4	then if it's not what you're looking for, please
5	A I do.	5	just ask me to clarify.
6	Q Okay. It says	6	I I see probably, you know, almost
7	MS. PARFITT: Let's get that up on the	7	every single kind of medical problem there is
8	ELMO.	8	because I I attend in so many different
9	BY MS. PARFITT:	9	locations within the Hopkins system. So meaning
10	Q All right. Do you see under "Overview,"	10	that I do work in the intensive care unit where
11	it says: "My research focuses on identifying	11	it's every kind of medical problem you could
12	factors that cause or provoke asthma. We have	12	imagine, it just happens to be the sickest of the
13	been interested especially in air pollutants,"	13	sick. So it could be any any organ system, or
14	parens, "particulate matter, NO2, secondhand	14	not even an organ system, but all sorts of
15	smoke," close parens, "and allergens," parens,	15	illnesses.
16	"including mouse," close parens, "that are	16	In the pulmonary clinic, I see I
17	especially problematic in inner city homes. We	17	certainly see people with asthma and COPD, but I
18	are studying the effects of these pollutants and	18	see pretty much any kind of pulmonary disease and
19	allergens on inflammation and oxidative stress.	19	get referrals for things that aren't pulmonary
20	More recently, we have begun examining how dietary	20	diseases. They they may be somebody who's got
21	patterns, especially a Western diet style a	21	a a symptom that turns out not to be a
22	Western-style diet, may increase susceptibility to	22	pulmonary disease.
23	inhalable pollutants and allergens."	23	In the oncology center, when I attend
24	Did I read that correctly?	24	there, I see every kind of cancer patient that at
25	A You did.	25	least that Hopkins sees.
	Page 103		Page 105
1	O Okay And then again under your	1	And then I'm also lucky enough to attend
1 2	Q Okay. And then again, under your	1 2	And then I'm also lucky enough to attend
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	Page 106		Page 108
1	not you were in our our unit or not.	1	certainly interested in pollutants.
2	Q So if I came in with a gynecological	2	Q Okay. And more recently, you've
3	problem, they might call you you, who are a	3	expressed a research interest in dietary patterns
4	pulmonologist, they might call you in to consult	4	particularly, and especially a Western diet and
5	with me?	5	how that might increase susceptibility to
6	MS. BROWN: Objection to the form of the	6	inhalable pollutants; is that correct?
7	question and the tone.	7	A True.
8	THE WITNESS: Well, I am picking up the	8	MS. BROWN: Form.
9	tone, which I which I think I mean, I know	9	BY MS. PARFITT:
10	you're trying to make a point here. And the	10	Q Are you have you published recently
11	question as you asked it is the answer is, of	11	on that?
12	course. But I think what you're trying to get at	12	A I'm sure there's stuff that's come out.
13	is would they have asked me to come deal with	13	Q Well, I only have your CV from 2017, so
14	their pregnancy, for example, and I wouldn't be	14	I'll represent that I'm not seeing something on
15	the person dealing with their pregnancy. I would	15	that CV.
16	be dealing with something else.	16	Is there something you've done recently?
17	BY MS. PARFITT:	17	A Yeah, it's a couple of years ago.
18	Q Okay. All right. Is it fair to say	18	Q Okay.
19	that your practice primarily deals with	19	A I mean the best way to find stuff would
20	individuals who have pulmonary and lung disease	20	be on PubMed.
21	conditions?	21	Q All right. You've been retained to
22	MS. BROWN: Objection.	22	serve as an expert for Johnson & Johnson, correct?
23	THE WITNESS: I think if you dial back	23	MS. BROWN: Form.
24	and listen to what I said for those other answers,	24	THE WITNESS: That's correct.
25	you would be pretty clear that it isn't just that.	25	BY MS. PARFITT:
	2 105		7 100
_	Page 107		Page 109
1	BY MS. PARFITT:	1	Q Okay. Do you know what the do you
2	Q Okay. Well, I would include asthma in	2	have an understanding of what the allegations are
3	that as well.	3	against Johnson & Johnson?
4	MS. BROWN: Same objection.	4	MS. BROWN: Objection to the form.
5	THE WITNESS: Well, include it, but I	5	THE WITNESS: Which which ones?
6	mean but, you know, when I'm on the general	6	BY MS. PARFITT:
7	internal medicine service, I'm not seeing mostly	7	Q Do you know why you're Johnson &
8	asthma. I might be seeing somebody with diabetes	8	Lohngon ig hoing guad'?
			Johnson is being sued?
9	or a heart attack or pelvic inflammatory disease,	9	MS. BROWN: Objection.
10	or a heart attack or pelvic inflammatory disease, you know, to name a GYN problem. I mean it's the	9 10	MS. BROWN: Objection. Counsel, are you asking a legal
10 11	or a heart attack or pelvic inflammatory disease, you know, to name a GYN problem. I mean it's the whole gamut from head to toe.	9 10 11	MS. BROWN: Objection. Counsel, are you asking a legal question?
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Gregory B. Diette, M.D.

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1	MS. BROWN: Objection.	1	through it quickly and just get a sense of what
2	THE WITNESS: I don't have any separate	2	the case is about.
3	understanding.	3	BY MS. PARFITT:
4	BY MS. PARFITT:	4	Q And then what do you do with it?
5	Q Okay. Do you know who Imerys are is	5	MS. BROWN: Form.
6	or are?	6	BY MS. PARFITT:
7	A I'm aware that it's a supply company of	7	Q Do you keep it?
8	some sort, but I don't know much more about them.	8	A Oh, not forever. I mean if the case is
9	Q All right. And do you have an	9	over, then I destroy it with all the other
10	understanding of the allegations against the	10	materials.
11	Personal Care Products Corporation	11	Q Well, this case is far from over.
12	MS. BROWN: Objection.	12	Have do you still have
13	BY MS. PARFITT:	13	MS. BROWN: Counsel, just ask the
14	Q otherwise known as the PCPC?	14	question.
15	MS. BROWN: Objection. Calls for	15	BY MS. PARFITT:
16	speculation.	16	Q a copy of the complaint?
17	THE WITNESS: I don't	17	MS. MILLER: You asked about a state
18	MR. LOCKE: Objection.	18	court case.
19	BY MS. PARFITT:	19	MS. PARFITT: No. I said was there
20	O You don't.	20	hey again, hey, ladies, I'm sorry, I think the
21	A I don't know who that is.	21	two of you are going to have to agree who is going
22	Q All right. Have you ever seen a	22	to com who's going to complain who's going
23	complaint in this case?	23	to object. One of you can object.
24	MS. BROWN: Objection.	24	MS. BROWN: Well, if you're going to
25	BY MS. PARFITT:	25	complain, I'm going to object.
23	B1 WS.17M(111.	23	complain, I'm going to object.
	Page 111		Page 113
1	Page 111  Q And when I say "this case," I'm talking	1	Page 113 MS. PARFITT: Okay.
1 2		1 2	
	Q And when I say "this case," I'm talking		MS. PARFITT: Okay.
2	Q And when I say "this case," I'm talking about this case of talcum powder products and	2	MS. PARFITT: Okay. MS. BROWN: Please just ask the
2	Q And when I say "this case," I'm talking about this case of talcum powder products and ovarian cancer, be it in an MDL context or a state	2 3	MS. PARFITT: Okay. MS. BROWN: Please just ask the question. No speeches.
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29 (Pages 110 to 113)

	Page 114		Page 116
1	MS. BROWN: We are complying with it.	1	THE WITNESS: Can you say it again?
2	We're happy to call the Judge.	2	BY MS. PARFITT:
3	MS. PARFITT: So the CMO says that you	3	Q Sure.
4	get to say, "Objection. Form." That's what you	4	A Yeah.
5	get to say.	5	Q Have you ever been provided
6	You have a wonderful opportunity at the	6	gynecological care or treatment for a woman who
7	end of this deposition to ask him as many	7	has been diagnosed with ovarian cancer?
8	questions as you like, but for right now, my time,	8	A So there's just a couple of things
9	my deposition. It's, "Objection. Form." And I	9	there, and I think maybe I heard it wrong.
10	really would appreciate that courtesy. I will	10	Did you say been provided care?
11	give it to you, but I would appreciate getting it	11	Q Have you ever provided
12	back. So	12	A Provided. Okay. I'm sorry. I thought
13	MS. BROWN: And to be clear	13	you said "been provided."
14	MS. PARFITT: No, Counsel, no more	14	Q No, no, no, no.
15	speeches. No more speeches.	15	MS. MILLER: You did say that.
16	MS. BROWN: You just made a speech, and	16	THE WITNESS: I thought it sounded like
17	I'm going to respond	17	did I get care. I was like
18	MS. PARFITT: No more speeches, Counsel.	18	MS. MILLER: You did
19	My deposition.	19	BY MS. PARFITT:
20	MS. BROWN: No, Counsel.	20	Q No, I I don't think you did.
21	MS. PARFITT: Not your deposition.	21	A Yeah, right.
22	BY MS. PARFITT:	22	Q I know, that would have been a very
23	Q Next question I have	23	awkward question, wouldn't it?
24	MS. PARFITT: No more questions,	24	Have you ever provided gynecological
25	Counsel. You want me to depose you?	25	care or treatment for a woman who has been
	Page 115		Page 117
1	MS. BROWN: Counsel, no. You are	1	diagnosed with ovarian cancer?
2	raising your tone.	2	A Sure. And I think it goes back to some
3	MS. PARFITT: Counsel	3	of the things I said before where I see people in
4	MS. BROWN: You are yelling at me.	4	the hospital who have ovarian cancer, and through
5	MS. PARFITT: you know what, I was	5	my training, you know, for medical school and
6	told a little bit earlier nobody could hear me.	6	residency, that was part of our training also,
7	So I have lifted my voice, and now I'm using my	7	which was to rotate on services where people
8	stage voice. So now everyone can hear me, and now	8	had every every imaginable illness.
9	I'm speaking too loud to you.	9	Q Okay. Well, your residency was how long
10	So I'm going to try you know, you	10	ago?
			-8-1
11	can't have it both ways. One speaker, one	11	MS. BROWN: Objection.
11 12	objectioner. Next question.	11 12	
			MS. BROWN: Objection.
12	objectioner. Next question.	12	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to
12 13	objectioner. Next question.  MS. BROWN: The record will reflect that	12 13	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you
12 13 14	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please	12 13 14	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT:
12 13 14 15	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:	12 13 14 15	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you
12 13 14 15 16	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?	12 13 14 15 16	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time.
12 13 14 15 16 17	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?  A I am not an oncologist.	12 13 14 15 16 17	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time. What I'm talking about is whether or not
12 13 14 15 16 17 18	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?  A I am not an oncologist.  Q Are you a radiation oncologist?	12 13 14 15 16 17 18	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time. What I'm talking about is whether or not you have actually provided gynecological care to a
12 13 14 15 16 17 18	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?  A I am not an oncologist.  Q Are you a radiation oncologist?  A No.	12 13 14 15 16 17 18 19	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time. What I'm talking about is whether or not you have actually provided gynecological care to a woman who presented to you with ovarian cancer?
12 13 14 15 16 17 18 19 20	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?  A I am not an oncologist.  Q Are you a radiation oncologist?  A No.  Q Are you a gynecologist?	12 13 14 15 16 17 18 19 20	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time. What I'm talking about is whether or not you have actually provided gynecological care to a woman who presented to you with ovarian cancer? MS. BROWN: Objection to the form.
12 13 14 15 16 17 18 19 20 21	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?  A I am not an oncologist.  Q Are you a radiation oncologist?  A No.  Q Are you a gynecologist?  A No.	12 13 14 15 16 17 18 19 20 21	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time. What I'm talking about is whether or not you have actually provided gynecological care to a woman who presented to you with ovarian cancer? MS. BROWN: Objection to the form. Asked and answered five times.
12 13 14 15 16 17 18 19 20 21	objectioner. Next question.  MS. BROWN: The record will reflect that you are making incessant speeches. Please BY MS. PARFITT:  Q Are you an oncologist, Dr. Diette?  A I am not an oncologist.  Q Are you a radiation oncologist?  A No.  Q Are you a gynecologist?  A No.  Q Okay. Have you ever provided	12 13 14 15 16 17 18 19 20 21 22	MS. BROWN: Objection. THE WITNESS: My residency was 1990 to 1993. BY MS. PARFITT: Q Okay. So I'm not talking about what you did in 1993, back in that period of time. What I'm talking about is whether or not you have actually provided gynecological care to a woman who presented to you with ovarian cancer? MS. BROWN: Objection to the form. Asked and answered five times. You can answer, Dr. Diette.

Gregory B. Diette, M.D.

	Page 118		Page 120
1	MS. BROWN: Same objection.	1	hygienist?
2	THE WITNESS: I think I know your	2	A No.
3	question, but could you be specific like	3	Q Okay. Are you what's referred to as a
4	BY MS. PARFITT:	4	mineralogist or a mineral scientist specialist?
5	Q Sure.	5	A Neither one.
6	A like just an example, and then I'll	6	Q Are you a geologist?
7	know that we're talking about the same thing.	7	A No.
8	Q Okay. Have you ever provided primary	8	Q Okay. Is it fair to say that you do not
9	care, gynecological care or treatment for a woman	9	hold yourself out in the scientific and medical
10	who has been diagnosed with ovarian cancer?	10	community as an expert with regard to testing
11	A So	11	standards of particulate matter, toxins or
12	MR. LOCKE: Objection.	12	carcinogens?
13	THE WITNESS: I'm not trying to	13	A I think that sounds right.
14	criticize the question, but primary care sounds	14	Q And that would include testing of
15	like something that a like a family	15	minerals or, excuse me, that would include
16	practitioner or an internist would do. I think	16	testing of asbestos?
17	you mean something else, so	17	MS. BROWN: Objection to the form.
18	BY MS. PARFITT:	18	THE WITNESS: Correct.
19	Q I do. Okay. What I'm talking about is	19	BY MS. PARFITT:
20	if I called up Johns Hopkins and said, I have been	20	Q And that would include testing of talcum
21	diagnosed with ovarian cancer, I need to see a	21	powder products?
22	physician, would I be referred to the pulmonology	22	A That I I don't do that, is that
23	department, your department, or would I be	23	right?
24	referred to a different department?	24	Q Right.
25	MS. BROWN: Objection to the form.	25	A Yeah, that's correct.
	<u> </u>		
	Page 119		Page 121
1	THE WITNESS: Different department,	1	Q All right. Let's talk a little bit
2	assuming it's literally for the care of the	2	about your publications and your research.
3	ovarian cancer.	3	Let me direct your attention to I
4	BY MS. PARFITT:	4	believe this is Appendix C of your CV, which I
5	Q Okay. Fair. Thank you.	5	believe is Exhibit 7.
6	Have you ever researched the life	6	Do you have that in front of you?
7	expectancy of a woman who has ovarian cancer?	7	
8		'	A I do.
U	A No.	8	A I do. Q Okay. I understand, now that I have a
9	A No. MS. BROWN: Objection to the form.		
		8	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167
9	MS. BROWN: Objection to the form.	8 9	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have,
9 10	MS. BROWN: Objection to the form. BY MS. PARFITT:	8 9 10	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167
9 10 11	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist?	8 9 10 11	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.
9 10 11 12	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not.	8 9 10 11 12	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?
9 10 11 12 13	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist?	8 9 10 11 12 13	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017.
9 10 11 12 13 14	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not.	8 9 10 11 12 13 14	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017. Q All right. So sitting here today in
9 10 11 12 13 14	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist?	8 9 10 11 12 13 14 15	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect? A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications
9 10 11 12 13 14 15	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No.	8 9 10 11 12 13 14 15 16	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect? A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published?
9 10 11 12 13 14 15 16 17	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No. Q Are you a toxicologist?	8 9 10 11 12 13 14 15 16 17	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published? A I think if you look on PubMed, you will
9 10 11 12 13 14 15 16 17	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No. Q Are you a toxicologist? A No.	8 9 10 11 12 13 14 15 16 17	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017.  Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published?  A I think if you look on PubMed, you will see more than 200.
9 10 11 12 13 14 15 16 17 18	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No. Q Are you a toxicologist? A No. Q Are you a pharmacologist? A No. A No. A No. A No. A No.	8 9 10 11 12 13 14 15 16 17 18 19	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published?  A I think if you look on PubMed, you will see more than 200. Q Okay. Is it fair to say that you've
9 10 11 12 13 14 15 16 17 18 19 20	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No. Q Are you a toxicologist? A No. Q Are you a pharmacologist? A No. Q Are you a pharmacologist? A No. Q Okay. Are you a regulatory expert?	8 9 10 11 12 13 14 15 16 17 18 19 20	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published?  A I think if you look on PubMed, you will see more than 200. Q Okay. Is it fair to say that you've published no papers or studies in the peer-
9 10 11 12 13 14 15 16 17 18 19 20 21	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No. Q Are you a toxicologist? A No. Q Are you a pharmacologist? A No. A No. A No. A No. A No.	8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published?  A I think if you look on PubMed, you will see more than 200. Q Okay. Is it fair to say that you've published no papers or studies in the peer- reviewed literature about asbestos or asbestos-
9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. BROWN: Objection to the form. BY MS. PARFITT: Q Are you a pathologist? A I am not. Q All right. And are you a radiologist? A I am not. Q Okay. Are you a mineralogist? A No. Q Are you a toxicologist? A No. Q Are you a pharmacologist? A No. Q Are you a pharmacologist? A No. Q Okay. Are you a regulatory expert? A I don't know what that means, but I don't I don't use those words to describe	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017. Q All right. So sitting here today in April of 2019, approximately how many publications in peer-reviewed journals have you published?  A I think if you look on PubMed, you will see more than 200. Q Okay. Is it fair to say that you've published no papers or studies in the peer- reviewed literature about asbestos or asbestos- related diseases? A Correct.
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. BROWN: Objection to the form.  BY MS. PARFITT:  Q Are you a pathologist?  A I am not.  Q All right. And are you a radiologist?  A I am not.  Q Okay. Are you a mineralogist?  A No.  Q Are you a toxicologist?  A No.  Q Are you a pharmacologist?  A No.  Q Are you a pharmacologist?  A No.  Q Okay. Are you a regulatory expert?  A I don't know what that means, but I	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q Okay. I understand, now that I have a CV that's dated June of 2017, and the CV I have, it says that you've published approximately 167 publications in peer-reviewed literature.  Is that correct or incorrect?  A It was probably true as of June 2017.  Q All right. So sitting here today in April of 2019, approximately how many publication in peer-reviewed journals have you published?  A I think if you look on PubMed, you will see more than 200.  Q Okay. Is it fair to say that you've published no papers or studies in the peer-reviewed literature about asbestos or asbestos-related diseases?

31 (Pages 118 to 121)

	Page 122		Page 124
1	Q Sure.	1	THE WITNESS: So that's a different
2	A I can help you just clarify what I	2	question. So the answer to that is no.
3	what I'm trying to answer.	3	BY MS. PARFITT:
4	Q Please.	4	Q All right. Have you published any
5	A So nothing about asbestos, but if you	5	papers in the peer-reviewed literature on
6	if you consider asbestos-related diseases to	6	mesothelioma?
7	include lung cancer, for example, that there are	7	A No.
8	publications that bear on lung cancer, and there's	8	Q All right. So nowhere in the 200
9	at least one article, maybe more, on interstitial	9	publications that you have prepared would I see
10	lung diseases, and asbestosis would be an	10	the word "mesothelioma"?
11	interstitial lung disease.	11	A I can't promise that you won't see that
12	Q Okay. Can you tell me what those	12	word in some paper, but there's not a paper whose
13	articles are?	13	primary topic is about mesothelioma.
14	A Let's see. Would the how do you want	14	Q All right. Very good.
15	me to do it, like the number?	15	Having reviewed your 200 or so
16	Q If you give me the number, that would be	16	publications, is it fair to say that there are no
17	fine.	17	peer-reviewed publications regarding the subject
18	A Yeah. So number 5 has to do with lung	18	matter of ovarian cancer?
19	cancer.	19	A That's correct.
20	Q Now, does that have to do with lung	20	Q Is it fair to say that none of your
21	cancer and asbestos exposure?	21	peer-reviewed papers address a diagnosis of
22	A No, not specifically.	22	ovarian cancer?
23	Q All right. So that has that is not	23	MS. BROWN: Objection. Form. I don't
24	lung cancer and asbestos.	24	understand that.
25	All right. Is there another one?	25	THE WITNESS: Well, I think I think
	Page 123		Page 125
1	A Yeah, so if you look at number 6, this	1	the answer to the one before encompasses, you
2	is, you know, a study about evaluating lung masses	2	know, something else with the word "ovarian
3	and large lymph nodes.	3	cancer" in the question.
4	Q Yes.	4	BY MS. PARFITT:
5	A So that would include, you know, lung	5	Q Okay. All right. Have you published
6	cancer in that as well.	6	any peer-reviewed publications that talk about the
7	Q Does that include asbestos and lung	7	causes of ovarian cancer?
8	cancer?	8	MS. BROWN: Objection.
9	A Not specifically.	9	THE WITNESS: No.
10	Q All right. Any others?	10	BY MS. PARFITT:
11	A I would say any of the ones where you	11	Q Have you published any peer-reviewed
12	see the word "bronchoscopy," it has something to	12	papers that talk about risk factors for ovarian
13	do with lung cancer for the most part, though not	13	cancer?
14	literally lung cancer and asbestos.	14	MS. BROWN: Same objection.
15	So, for example, like 21, number 2,	15	THE WITNESS: No.
16	number 3, you know, all sort of have some bearing	16	BY MS. PARFITT:
17	on at least the you know, the care or	17	Q Have you published any publications in
18	management of people with suspected lung cancer or	18	the peer-reviewed journal on risk factors for
19	who actually have lung cancer.	19	mesothelioma?
20	Q Dr. Diette, my question is very specific	20	A No.
21	to publications in the peer-reviewed journal that	21	Q What causes mesothelioma?
22	deal with the topic of asbestos or asbestos-	22	A A few things. You know, asbestos in
23	related diseases like lung cancer where the word	23	sufficient dose can do it. Radiation can do it.
24	"asbestos" appears in your publication.	24	There's some other minerals that aren't asbestos
Ì			
25	MS. BROWN: Objection to the form.	25	that are suspected to do it. It can arise on its

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	Page 126		Page 128
1	own spontaneously. And, you know, there's	1	A Right, are there no.
2	thoughts of, at least in the peritoneum, about	2	Q Okay. I noted in your CV or in some of
3	certain kinds of chronic inflammation that may	3	the readings that you are currently involved in
4	lead to that as well.	4	some clinical trials.
5	Q Okay. Can asbestos cause lung cancer?	5	Did I did I get that correct?
6	A Yes. In a sufficient dose.	6	A I have been involved in trials.
7	Q Okay. Is it fair to say that you have	7	Q Something recent?
8	not published in the peer-reviewed literature any	8	A Oh, all the time.
9	studies on talcum powder products as a causative	9	Q Okay. Are you currently involved in any
10	factor for ovarian cancer?	10	clinical trial
11	A That is correct.	11	A Yeah.
12	Q Is it fair to say that you have not	12	Q trials?
13	published in the peer-reviewed journal any studies	13	Okay. Do any of them deal with the
14	with regard to talcum powder products as a risk	14	subject of asbestos?
15	factor for ovarian cancer?	15	A No.
16	A That's correct.	16	Q Do any of your trials or research deal
17	Q Is it fair to say to say that there are	17	with the subject of talcum powder products?
18	no publications in your peer-reviewed literature	18	A No.
19	on the subject of talcum of talc as a source of	19	Q All right. Do you currently have
20	asbestos fibers?	20	ongoing any research work in the area of asbestos?
21	MS. BROWN: Objection. Counsel, I think	21	MS. BROWN: Objection to the form.
22	you just misspoke. Do you mean on his CV?	22	THE WITNESS: No.
23	MS. PARFITT: I'm sorry? I did.	23	BY MS. PARFITT:
24	BY MS. PARFITT:	24	Q Do you currently have ongoing in any of
25	Q Is it fair to say	25	your research work on the topic of mesothelioma?
	Page 127		Page 129
1	MS. PARFITT: Thank you.	1	A No.
2	BY MS. PARFITT:	2	Q Do you currently have any research work
2 3	BY MS. PARFITT:  Q Is it fair to say that there are no	2	Q Do you currently have any research work ongoing on the topic of talcum powder products?
	Q Is it fair to say that there are no		
3		3	ongoing on the topic of talcum powder products?  A No.
3 4	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss	3 4	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in
3 4 5	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos	3 4 5	ongoing on the topic of talcum powder products?  A No.
3 4 5 6	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.	3 4 5 6	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on
3 4 5 6 7	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.  Q Is it fair to say there are no	3 4 5 6 7	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on ovarian cancer?  A No.
3 4 5 6 7 8 9	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.  Q Is it fair to say there are no publications in a peer-reviewed journal contained	3 4 5 6 7 8	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on ovarian cancer?
3 4 5 6 7 8 9	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.  Q Is it fair to say there are no publications in a peer-reviewed journal contained in your curriculum vitae regarding the association	3 4 5 6 7 8	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on ovarian cancer?  A No.  MS. BROWN: Objection to the form.  BY MS. PARFITT:
3 4 5 6 7 8	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.  Q Is it fair to say there are no publications in a peer-reviewed journal contained	3 4 5 6 7 8 9	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on ovarian cancer?  A No.  MS. BROWN: Objection to the form.  BY MS. PARFITT:  Q Okay. Would it be fair to say that the
3 4 5 6 7 8 9 10	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.  Q Is it fair to say there are no publications in a peer-reviewed journal contained in your curriculum vitae regarding the association or relationship between talcum powder products and ovarian cancer?	3 4 5 6 7 8 9 10	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on ovarian cancer?  A No.  MS. BROWN: Objection to the form.  BY MS. PARFITT:  Q Okay. Would it be fair to say that the only report that you have prepared on the topic of
3 4 5 6 7 8 9 10 11 12	Q Is it fair to say that there are no peer-reviewed publications in your CV that discuss the subject as of talc as a source of asbestos fibers?  A Correct.  Q Is it fair to say there are no publications in a peer-reviewed journal contained in your curriculum vitae regarding the association or relationship between talcum powder products and	3 4 5 6 7 8 9 10 11 12	ongoing on the topic of talcum powder products?  A No.  Q Do you currently have any research in the works with regard to work on work on ovarian cancer?  A No.  MS. BROWN: Objection to the form.  BY MS. PARFITT:  Q Okay. Would it be fair to say that the only report that you have prepared on the topic of talcum powder products and ovarian cancer would be
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	Page 134		Page 136
1	A That's this	1	BY MS. PARFITT:
2	Q Do you see that?	2	Q That's correct.
3	A That's this one for here?	3	A Oh, yeah, so then, no, nothing
4	Q Correct.	4	nothing for which I've been disclosed.
5	A Yes.	5	Q Okay. But I take it that you have been
6	Q All right. Now, you've identified on	6	retained you're currently retained to work on
7	the record that the report I have handed you,	7	some other cases other than talcum powder products
8	which is Exhibit No. 10, is a copy of your federal	8	and ovarian cancer, is that correct, by Johnson &
9	court expert report in the matter of dealing	9	Johnson?
10	with the issues of talc and ovarian cancer,	10	MS. BROWN: Counsel, I'm going to to
11	correct?	11	the extent you're asking about consulting
12	A Exactly right.	12	engagements, I'm going to instruct him not to
13	Q And in addition to that report, you have	13	answer.
14	prepared some affidavits in the past also	14	BY MS. PARFITT:
15	addressing the topic of talcum powder products and	15	Q No, I'm asking this: Are you an expert
16	ovarian cancer, correct?	16	on behalf of Johnson & Johnson and asbestos and
17	A That's correct.	17	and ovarian cancer cases?
18	Q Okay. Have you prepared any reports on	18	A So there's a subtlety there, right,
19	talcum powder products and ovarian cancer outside	19	because I mean you may call this an asbestos
20	of the legal context?	20	and ovarian cancer case. I think it's a talcum
21	MS. BROWN: Objection to the form.	21	powder and ovarian cancer case.
22	THE WITNESS: No.	22	Q Okay.
23	BY MS. PARFITT:	23	A There's nothing that's about asbestos
24	Q Okay. And have you provided any other	24	separately from what we're talking about here.
25	type of written report in a legal context, aside	25	Q Fair enough. Have you been retained by
	type of whiteh report in a regar content, uside		Q Tan chaugh. There you occurrenamed by
	Page 135		Page 137
1	from affidavits and the MDL report that you have	1	Johnson & Johnson to testify as a legal expert in
2	in front of you?	2	any talcum powder product cases and meso
3	MS. BROWN: Form.	3	mesothelioma?
4	BY MS. PARFITT:	4	A Yes.
5	Q On talcum powder products and ovarian	5	Q Okay. Are you currently an expert in
6	cancer. I'm just trying to find out your world.	6	any of those cases?
7	A No, I understand. And I'm not sure if	7	A Yes.
8	there could be like a work in progress. But	8	Q How many?
9	you're talking about completed, completed like	9	MS. BROWN: And again, Doctor, to the
10	products like this, right?	10	extent you've been disclosed, you can answer the
11	Q Correct.	11	question.
12	A I I can't think of another one.	12	THE WITNESS: So I don't I don't know
13	Q Okay. Do you have another report and/or	13	the count then. I would estimate ten, but I could
14	affidavit in progress in the talcum powder	14	be off by a couple.
15	products cases and ovarian cancer?	15	BY MS. PARFITT:
i	MS. BROWN: Dr. Diette, I'm going to	16	Q Have you given depositions in those
16	instruct you to the extent you're doing any work	17	cases yet?
16 17	monate jour to the entent jours doing any work	I	
		18	A In some cases I have.
17	on this issue that is in a consulting nature and	18 19	
17 18			Q Okay. Is this the first deposition that
17 18 19 20	on this issue that is in a consulting nature and has not been disclosed, you should not disclose that here.	19 20	Q Okay. Is this the first deposition that you have given in talcum powder products and
17 18 19 20 21	on this issue that is in a consulting nature and has not been disclosed, you should not disclose that here.  I assume counsel is only asking for	19 20 21	Q Okay. Is this the first deposition that you have given in talcum powder products and ovarian cancer?
17 18 19 20 21 22	on this issue that is in a consulting nature and has not been disclosed, you should not disclose that here.  I assume counsel is only asking for situations in which you have been disclosed as an	19 20 21 22	Q Okay. Is this the first deposition that you have given in talcum powder products and ovarian cancer?  MS. BROWN: Objection.
17 18 19 20 21 22 23	on this issue that is in a consulting nature and has not been disclosed, you should not disclose that here.  I assume counsel is only asking for situations in which you have been disclosed as an expert, and with that, you can answer the	19 20 21	Q Okay. Is this the first deposition that you have given in talcum powder products and ovarian cancer?  MS. BROWN: Objection.  THE WITNESS: I don't think so.
17 18 19 20 21 22	on this issue that is in a consulting nature and has not been disclosed, you should not disclose that here.  I assume counsel is only asking for situations in which you have been disclosed as an	19 20 21 22 23	Q Okay. Is this the first deposition that you have given in talcum powder products and ovarian cancer?  MS. BROWN: Objection.

Gregory B. Diette, M.D.

	Page 138		Page 140
1	Ingham case?	1	yes.
2	A I did.	2	Q Okay. The last date I have here is
3	Q Okay. Did you testify at trial at the	3	September 28, '18.
4	Ingham case?	4	A No. It should go further.
5	A I did not.	5	MS. BROWN: We have another page,
6	Q Okay. Is there any other case other	6	Counsel.
7	than the Ingham case where you have given	7	MS. PARFITT: Okay.
8	deposition in an ovarian cancer and a talcum	8	THE WITNESS: I think it's two-sided, so
9	powder case?	9	it's the back of that page.
10	A I think there's at least one other one.	10	MS. PARFITT: Okay. Well
11	Q Okay. Do you remember the name of it?	11	MS. BROWN: Do you want my copy?
12	A I don't. I could look at my testimony	12	MS. PARFITT: That would be great. I
13	list and see if I can figure it out.	13	appreciate that. I will give it right back to
14	Q Okay. And we'll have that marked as	14	you.
15	well. Why don't we have that marked as Diette	15	BY MS. PARFITT:
16	Exhibit it's part of your exhibit number	16	Q Okay. All right. So the last date is
17	it's part of your report, but we'll have it marked	17	February 22nd, 2019; is that correct?
18	as a separate exhibit.	18	A That is.
19	(Counsel conferring.)	19	Q All right. Are you able to circle for
20	BY MS. PARFITT:	20	me which cases are cases in which you have been
21	Q Let me show you what's we'll have	21	retained as an expert in the on the topic of
22	marked as Exhibit No. 11.	22	talcum powder products and ovarian cancer?
23	(Diette Exhibit No. 11 was marked	23	MS. BROWN: Objection to the form.
24	for identification.)	24	You can answer to the extent you know,
25	BY MS. PARFITT:	25	Doctor.
23	BI Mo. I Mai III.		Doctor.
	Page 139		D 141
	rage 137		Page 141
1		1	THE WITNESS: I actually don't. I'd
1 2		1 2	
	Q All right. Let me show you what's		THE WITNESS: I actually don't. I'd
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36 (Pages 138 to 141)

	Page 142		Page 144
1	those cohort studies?	1	MS. BROWN: Wait. Hold on. Is that a
2	A Generally speaking, things related to	2	question?
3	respiratory diseases and and things people	3	MS. PARFITT: Mm-hmm.
4	inhale.	4	MS. BROWN: I didn't understand that.
5	Q All right. Have you published case-	5	If you understood it, you can answer.
6	control studies?	6	THE WITNESS: Well, the papers I was
7	A I don't know. I can't think of one. It	7	thinking about had to do with methods and
8	doesn't mean that there isn't one, but I'm I	8	quality quality assessment in terms of
9	can't think of a case-control study.	9	healthcare.
10	Q All right. Is it fair to say that none	10	BY MS. PARFITT:
11	of the published cohort studies address the issue	11	Q Okay.
12	of talcum powder products and ovarian cancer?	12	A I don't know if I've published anything
13	A Correct.	13	on epi methods, meaning like, you know, the topic
14	Q And is it fair to say that none of the	14	of a case-control study or
15	cohort studies that you published address the	15	Q Right.
16	issue of talcum powder products and mesothelioma?	16	A cohort studies, things of that sort.
17	A Correct.	17	Q So it would be fair to say that you have
18	Q Is it fair to say that none of the	18	not published in a peer-reviewed journal a paper
19	cohort studies that you have published address the	19	on study designs, correct?
20	issue of asbestos and mesothelioma?	20	MS. BROWN: Objection to the form.
21	A Correct.	21	THE WITNESS: I would have to look back
22	Q Is it fair to say that that the	22	and see. I mean it's it's possible I've been
23	majority of your publications in your listed in	23	involved in something that that I mean it's
24	your curriculum CV and those that you said you	24	just hard to remember. It's 200 plus papers,
25	have published since 2017 deal primarily in the	25	SO
	1 ,		
		1	
	Page 143		Page 145
1	Page 143 research interests of lung disease, COPD,	1	Page 145 BY MS. PARFITT:
1 2		1 2	
	research interests of lung disease, COPD,		BY MS. PARFITT:
2	research interests of lung disease, COPD, asthma	2	BY MS. PARFITT:  Q Right. So nothing you can remember
2 3	research interests of lung disease, COPD, asthma MS. BROWN: Objection	2 3	BY MS. PARFITT:  Q Right. So nothing you can remember today.
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2 3 4 5 6	research interests of lung disease, COPD, asthma MS. BROWN: Objection BY MS. PARFITT: Q pulmonary medicine, lung diseases? MS. BROWN: Objection to the form.	2 3 4 5 6	BY MS. PARFITT:  Q Right. So nothing you can remember today.  A Correct.  Q Okay. And have you published on the Bradford Hill factors?
2 3 4 5 6 7	research interests of lung disease, COPD, asthma MS. BROWN: Objection BY MS. PARFITT: Q pulmonary medicine, lung diseases? MS. BROWN: Objection to the form. THE WITNESS: There's certainly plenty	2 3 4 5 6 7	BY MS. PARFITT: Q Right. So nothing you can remember today. A Correct. Q Okay. And have you published on the Bradford Hill factors? MS. BROWN: Form.
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Gregory B. Diette, M.D.

	Page 146		Page 148
1	you did file in the federal court, you stated	1	different than what you asked? Because I'm
2	specifically that you followed the Bradford Hill	2	just
3	framework. Do you recall saying that?	3	BY MS. PARFITT:
4	A I I do. There was more to it, but it	4	Q It is.
5	included that.	5	This would be some original research
6	Q Okay. So what I'm asking you, in any of	6	that you might be got a funding or a grant or
7	the papers, whether they be cohort study, case	7	something.
8	control, other research and scientific	8	A I see. Nothing like that.
9	publications that you've listed on your curriculum	9	Q Okay. Have you received any funds
10	vitae, have you stated in those papers that you	10	any funding or any grants to study mesothelioma?
11	are following or are guided by the Bradford Hill	11	A No.
12	framework?	12	Q Have you received any funding or grants
13	MS. BROWN: Objection. He just answered	13	to study asbestos?
14	that.	14	A No.
15	THE WITNESS: Yeah, it's sort of baked	15	Q Have you received any funding or grants
16	into what we do. So it's like in I mean the	16	to study talcum powder products and their
17	answer is no, generally, but but we include	17	association with ovarian cancer?
18	things in a way that they fit with what Bradford	18	MS. BROWN: Objection to the form.
19	Hill considerations are. But there's not one that	19	THE WITNESS: No.
20	was called like the Bradford Hill approach or	20	BY MS. PARFITT:
21	something.	21	Q Have you ever published in peer-reviewed
22	BY MS. PARFITT:	22	literature a causation analysis or a review
23	Q Okay. And by	23	article asking whether an exposure causes a
24	MS. BROWN: Let him finish.	24	disease?
25	Were you finished, Doctor?	25	MS. BROWN: Objection to the form of the
	Page 147		Page 149
1	THE WITNESS: I'm okay. Thank you.	1	question.
2	MS. PARFITT: Thank you.	2	THE WITNESS: I don't know. I would
3	BY MS. PARFITT:	3	have to look back over. I don't like I don't
4	Q Assume I did a search of the word	4	know if I would use those words "causation
5	"Bradford Hill" in the 167 papers that you have		
6		5	analysis. Dut we certainly write did you say
6	published in the peer-reviewed journal, would it	6	analysis," but we certainly write did you say review article?
6 7	published in the peer-reviewed journal, would it surprise you if those words did not appear?		review article?
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7	surprise you if those words did not appear?  MS. BROWN: Objection to the form.	6 7	review article? BY MS. PARFITT: Q Yes.
7 8	surprise you if those words did not appear?  MS. BROWN: Objection to the form.  THE WITNESS: It wouldn't surprise me,	6 7 8	review article? BY MS. PARFITT: Q Yes. A So I don't write many review articles.
7 8 9	surprise you if those words did not appear?  MS. BROWN: Objection to the form.	6 7 8 9	review article? BY MS. PARFITT: Q Yes. A So I don't write many review articles. They're really they're really low quality
7 8 9 10	surprise you if those words did not appear?  MS. BROWN: Objection to the form.  THE WITNESS: It wouldn't surprise me, but I I don't know that it's not there somewhere. And I would search more broadly than	6 7 8 9 10	review article? BY MS. PARFITT: Q Yes. A So I don't write many review articles. They're really they're really low quality academic products for the most part, and so I try
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	surprise you if those words did not appear?  MS. BROWN: Objection to the form.  THE WITNESS: It wouldn't surprise me, but I I don't know that it's not there somewhere. And I would search more broadly than just those 167. I would look at the more recent ones too. I mean I can't say that it's not there, but there's not a paper about Bradford Hill. BY MS. PARFITT:  Q Okay. Have you been involved in any original research on asbestos in general?  MS. BROWN: Objection to the form.  THE WITNESS: I have not.  BY MS. PARFITT:  Q Have you have you conducted any	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	review article? BY MS. PARFITT: Q Yes. A So I don't write many review articles. They're really they're really low quality academic products for the most part, and so I try to focus more on original research. Q All right. Well, same question applied to original research. MS. BROWN: Objection to the form. THE WITNESS: Well, it wouldn't be I mean that wouldn't be an original research article. BY MS. PARFITT: Q Okay. Have you ever performed any research on the environmental impacts of talcum

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BY MS. PARFITT:  Q Environmental impacts of diseases is something is a topic that you are interesting in, correct?  A I am. Q You've studied the impact of environmental effects on lung diseases, correct? A I have. Q In fact, that's something you continue to be interested in, correct? A I am. Q But you've not studied any environmental impacts on ovarian cancer, correct? A Correct. MS. BROWN: Asked and answered. BY MS. PARFITT: Q Would it be fair to say that prior to being retained by Johnson & Johnson sometime in 2017, you had done no research on the issue of talcum powder products and ovarian cancer? MS. BROWN: Objection to the form, misstates his testimony.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q And to give you some a reference, we'll spend a little time on that before we get into your report. All right? Fair?  A Sounds good. Q Okay. What is Medical Science Affiliates? A I think they they call themselves an environmental consulting company. Q How long have you been involved with Medical Science Affiliates? MS. BROWN: Form. THE WITNESS: So involved, I guess we'll have to sort, but I I've known about them and done some work with them for about ten years. BY MS. PARFITT: Q Okay. And I too want to sort, so let me ask you this: When were you first introduced to Medical Science Affiliates? A Well, I guess if it's ten years, it would have been about ten years ago. Q And what were how did it come about
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MS. BROWN: Objection to the form, misstates his testimony.	21	Q And what were how did it come about
misstates his testimony.	22	
<u>-</u>		that you learned of a group called Medical Science
THE WITNESS: I think it's the same as	23	Affiliates?
	24	A There was a woman who worked there
		then I don't remember what her name is, she's
		,
Page 151		Page 153
BY MS. PARFITT:	1	not there anymore and she knew a colleague of
Q So it was not until you were retained by	2	mine, and they were I think at the time looking
Johnson & Johnson that you conducted any research	3	for somebody to take on an epidemiology project, a
on the topic of ovarian cancer and talcum powder	4	review. And so he he sent around like a note
products, correct?	5	or talked to us, I don't remember how he did it,
MS. BROWN: Objection to the form,	6	but to see if anybody was interested in in
misstates his testimony.	7	doing an epidemiology project.
THE WITNESS: That is right.	8	Q Who was that colleague?
MS. PARFITT: Okay. And is now a good	9	A I think it was Hank Fessler, but I could
time for a bio break or is it	10	be wrong. That's a while ago.
MS. PARFITT: Sure.	11	Q And what is his position within the
THE WITNESS: If you're in the middle of	12	university?
something, I	13	A He works in pulmonary.
MS. PARFITT: No, no, this is fine.	14	Q Okay. So you were you were then
We'll just move into another area quickly, yeah.	15	engaged by Medical Science Affiliates to do an
THE VIDEOGRAPHER: The time is	16	epidemiological report for them?
11:14 a.m., and we're going off the record.	17	MS. BROWN: Objection. Misstates
(Recess.)	18	testimony.
THE VIDEOGRAPHER: The time is	19	THE WITNESS: I don't know about
11:24 a.m., and we are back on the record.	20	engaged. I mean my my relationship is as an
BY MS. PARFITT:	21	independent contractor. So it's like it's not
	22	like I have an agreement to do anything with them
	23	or for them. But that's that's the place
	24	where, you know, they organize the materials for
_	25	me to look over and to and to do the
	BY MS. PARFITT:  Q So it was not until you were retained by Johnson & Johnson that you conducted any research on the topic of ovarian cancer and talcum powder products, correct?  MS. BROWN: Objection to the form, misstates his testimony.  THE WITNESS: That is right.  MS. PARFITT: Okay. And is now a good time for a bio break or is it  MS. PARFITT: Sure.  THE WITNESS: If you're in the middle of something, I  MS. PARFITT: No, no, this is fine.  We'll just move into another area quickly, yeah.  THE VIDEOGRAPHER: The time is  11:14 a.m., and we're going off the record.  (Recess.)  THE VIDEOGRAPHER: The time is	Page 151  BY MS. PARFITT:  Q So it was not until you were retained by Johnson & Johnson that you conducted any research on the topic of ovarian cancer and talcum powder products, correct?  MS. BROWN: Objection to the form, misstates his testimony.  THE WITNESS: That is right.  MS. PARFITT: Okay. And is now a good time for a bio break or is it  MS. PARFITT: Sure.  THE WITNESS: If you're in the middle of something, I  MS. PARFITT: No, no, this is fine.  We'll just move into another area quickly, yeah.  THE VIDEOGRAPHER: The time is 11:14 a.m., and we're going off the record.  (Recess.)  THE VIDEOGRAPHER: The time is 11:24 a.m., and we are back on the record.  BY MS. PARFITT:  Q All right. Dr. Diette, I want to talk for a moment about Medical Science Affiliates.  All right?

	Page 154		Page 156
1	epidemiological review.	1	Q More 50?
2	BY MS. PARFITT:	2	A At least 50.
3	Q Okay. Your counsel has objected, as you	3	Q Okay. And what has been the topic of
4	heard, to me obtaining a copy of your agreement,	4	those reports that you have prepared for Medical
5	so I'm going to have to ask you a few more	5	Science Affiliates' clients?
6	questions about this.	6	MS. BROWN: And I'm going to jump in
7	What is your arrangement with Medical	7	here. To the extent that those projects are
8	Science Affiliates? Independent contractor?	8	governed by confidentiality agreements, I would
9	A That's exactly right.	9	ask Dr. Diette that you only disclose that which
10	MS. BROWN: He just said it.	10	has been disclosed publicly, for example, in court
11	MS. PARFITT: Okay. I understand. You	11	or at a deposition.
12	can take your own deposition, Counsel. It's going	12	MS. PARFITT: Please stop coaching the
13	to show up on the record too, you're rubbing your	13	witness.
14	head.	14	BY MS. PARFITT:
15	BY MS. PARFITT:	15	Q Can you answer?
16	Q Medical Science, you have an independent	16	MS. BROWN: We're trying to protect
17	contract relationship, to do what?	17	confidentiality.
18	A I think what it establishes is that I	18	MS. PARFITT: I get
19	can use their administrative services as kind of	19	MS. BROWN: I'm instructing him on
20	like an outside office for me to do work.	20	privilege.
21	Q Okay. So that's one role, they're an	21	MS. PARFITT: That's fine. I
22	outside office. You mentioned, though, that they	22	understood. He can talk now.
23	contracted you to also write an epidemiology	23	THE WITNESS: So I would say that most
24	report. Correct?	24	of the work is in the context of what Ms. Brown
25	A It's	25	said, which is that it wasn't for me to share with
25	A its	23	said, which is that it wasn't for the to share with
	Page 155		
	rage 133		Page 157
1	MS. BROWN: Objection to the form.	1	Page 157 other people.
1 2		1 2	
	MS. BROWN: Objection to the form. THE WITNESS: It's incorrect. BY MS. PARFITT:		other people.
2	MS. BROWN: Objection to the form. THE WITNESS: It's incorrect. BY MS. PARFITT: Q Okay. Straighten it out for me.	2	other people. BY MS. PARFITT:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. BROWN: Objection to the form. THE WITNESS: It's incorrect.  BY MS. PARFITT: Q Okay. Straighten it out for me. A Well, they didn't contract me to do anything. They asked if I was interested in doing this epidemiologic project for a client that they knew of. Q Okay. That helps me. So Medical Science Affiliates reached out requested that you do an epidemiological report for one of their clients. A Exactly right. Q Okay. Over the course of ten years that you've been affiliated as an independent contractor with Medical Science Affiliates, how many times have you prepared a report for one of Medical Science Affiliates' clients? A I don't know. Q More than ten? A Sure.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	other people. BY MS. PARFITT: Q All right. Is J&J a client of Medical Science Affiliates? A I don't know what their relationship is, like I don't know if you would call them a client or not. Q Okay. Does Medical Science Affiliates do some work for Johnson & Johnson? MS. BROWN: Objection. Speculation. THE WITNESS: So I can tell you about what they do for me with regard to Johnson & Johnson. I don't know about anything else. BY MS. PARFITT: Q All right. Tell me what you know. A Well, like, for example, like in the cases that we've discussed that involve Johnson & Johnson, they've provided a service by collecting the materials, right. So, for example, like when you see that list of materials that that I provided that I reviewed, they will collect those
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. BROWN: Objection to the form. THE WITNESS: It's incorrect.  BY MS. PARFITT:  Q Okay. Straighten it out for me. A Well, they didn't contract me to do anything. They asked if I was interested in doing this epidemiologic project for a client that they knew of. Q Okay. That helps me. So Medical Science Affiliates reached out requested that you do an epidemiological report for one of their clients. A Exactly right. Q Okay. Over the course of ten years that you've been affiliated as an independent contractor with Medical Science Affiliates, how many times have you prepared a report for one of Medical Science Affiliates' clients? A I don't know. Q More than ten? A Sure. Q More than a hundred? A A hundred would be pushing it. So	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	other people. BY MS. PARFITT: Q All right. Is J&J a client of Medical Science Affiliates? A I don't know what their relationship is, like I don't know if you would call them a client or not. Q Okay. Does Medical Science Affiliates do some work for Johnson & Johnson? MS. BROWN: Objection. Speculation. THE WITNESS: So I can tell you about what they do for me with regard to Johnson & Johnson. I don't know about anything else. BY MS. PARFITT: Q All right. Tell me what you know. A Well, like, for example, like in the cases that we've discussed that involve Johnson & Johnson, they've provided a service by collecting the materials, right. So, for example, like when you see that list of materials that that I provided that I reviewed, they will collect those and and organize them for me. If there's a need to have a meeting or a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. BROWN: Objection to the form. THE WITNESS: It's incorrect.  BY MS. PARFITT: Q Okay. Straighten it out for me. A Well, they didn't contract me to do anything. They asked if I was interested in doing this epidemiologic project for a client that they knew of. Q Okay. That helps me. So Medical Science Affiliates reached out requested that you do an epidemiological report for one of their clients. A Exactly right. Q Okay. Over the course of ten years that you've been affiliated as an independent contractor with Medical Science Affiliates, how many times have you prepared a report for one of Medical Science Affiliates' clients? A I don't know. Q More than ten? A Sure. Q More than a hundred?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	other people. BY MS. PARFITT: Q All right. Is J&J a client of Medical Science Affiliates? A I don't know what their relationship is, like I don't know if you would call them a client or not. Q Okay. Does Medical Science Affiliates do some work for Johnson & Johnson? MS. BROWN: Objection. Speculation. THE WITNESS: So I can tell you about what they do for me with regard to Johnson & Johnson. I don't know about anything else. BY MS. PARFITT: Q All right. Tell me what you know. A Well, like, for example, like in the cases that we've discussed that involve Johnson & Johnson, they've provided a service by collecting the materials, right. So, for example, like when you see that list of materials that that I provided that I reviewed, they will collect those and and organize them for me.

	Page 158		Page 160
1	they were able to help sort my through my	1	you said, which is that they billed somebody else
2	schedule, you know, with me, and figure out a day	2	for the work that they did.
3	or days, I don't remember what we offered, things	3	BY MS. PARFITT:
4	of that sort. They'll prepare invoices on my	4	Q Do you know who that somebody else is?
5	behalf. They'll help edit a report. You know,	5	And I want to remind you you're under oath,
6	administrative type things.	6	Dr. Diette.
7	Q Okay. Let's break that down a little	7	MS. BROWN: What
8	bit.	8	THE WITNESS: What's
9	Is it your understanding that Medical	9	MS. BROWN: Whoa, whoa, whoa. I'm
10	Science Affiliates bills Johnson & Johnson	10	objecting to the implication there. Dr. Diette
11	MS. BROWN: Object	11	has done nothing but testify truthfully today.
12	BY MS. PARFITT:	12	MS. PARFITT: Counsel, objection, form.
13	Q and invoices them for work?	13	I'm telling you.
14	MS. BROWN: Objection to the form, calls	14	BY MS. PARFITT:
15	for speculation.	15	Q Please go on, Dr. Diette.
16	BY MS. PARFITT:	16	MS. BROWN: No, but what you just said
17	Q If you know.	17	is inappropriate
18	A I don't know where the bill goes because	18	MS. PARFITT: It was not
19	I don't know if it goes to the law firm. Like if	19	MS. BROWN: and it violates both the
20	it matters to you whether it's directly to Johnson	20	federal rules
21	& Johnson or I mean I can only guess that, you	21	MS. PARFITT: violative of anything,
22	know, the law firm is not going to pay the bill	22	Counsel.
23	out of their own pocket. They're probably going	23	MS. BROWN: as well as deposition
24	to then invoice Johnson & Johnson, but I don't	24	protocol. He of course is testifying under oath,
25	know whether the bill goes directly to Johnson &	25	and if you're suggesting something otherwise,
	know whether the onl goes directly to somison &		
	Page 159		Page 161
1	Johnson or whether it goes to the law firm.	1	that's wildly inappropriate.
2	Q All right.	2	MS. PARFITT: Counsel, let the Court
3	MS. BROWN: And, Doctor, counsel doesn't	3	decide if it's I think the Court might decide
4	want you to guess, so just answer the question the	4	that your objections and your manner today are
5	best	5	wildly inappropriate.
6	BY MS. PARFITT:	6	BY MS. PARFITT:
7	Q Dr. Diette, if they Medical Science	7	Q So, Dr. Diette, so we can move forward,
8	Affiliates collects material for you as you say	8	do you remember the question?
9	they did, correct?	9	A I remember it, but I think I already
10	A That's correct.	10	answered it. It's I don't have a better answer
11	Q do they bill you or do they bill	11	than what I gave you before.
12	someone else?	12	Q You don't know who Medical Science
13	MS. BROWN: Objection to the form.	13	billed for the services they rendered to you?
13 14	MS. BROWN: Objection to the form. THE WITNESS: They bill someone else.	13 14	billed for the services they rendered to you?  A Well, let's look at the invoice if we
14	THE WITNESS: They bill someone else.	14	A Well, let's look at the invoice if we
14 15	THE WITNESS: They bill someone else. BY MS. PARFITT:	14 15	A Well, let's look at the invoice if we want to. If it's on the top of that, then I
14 15 16	THE WITNESS: They bill someone else. BY MS. PARFITT: Q Okay. So when you testified that J&J	14 15 16	A Well, let's look at the invoice if we want to. If it's on the top of that, then I might
14 15 16 17	THE WITNESS: They bill someone else.  BY MS. PARFITT:  Q Okay. So when you testified that J&J excuse me, when you testified that you had	14 15 16 17	A Well, let's look at the invoice if we want to. If it's on the top of that, then I might Q It's been blacked out, Dr. Diette.
14 15 16 17 18	THE WITNESS: They bill someone else.  BY MS. PARFITT:  Q Okay. So when you testified that J&J excuse me, when you testified that you had assistance with regard to the preparation of some	14 15 16 17 18	A Well, let's look at the invoice if we want to. If it's on the top of that, then I might Q It's been blacked out, Dr. Diette. A So it's either a law firm or it's
14 15 16 17 18 19	THE WITNESS: They bill someone else.  BY MS. PARFITT:  Q Okay. So when you testified that J&J excuse me, when you testified that you had assistance with regard to the preparation of some of the materials that accompany your report, that was work that you contracted with Medical Service	14 15 16 17 18 19	A Well, let's look at the invoice if we want to. If it's on the top of that, then I might Q It's been blacked out, Dr. Diette. A So it's either a law firm or it's Johnson & Johnson. I don't know whether it's one or the other.
14 15 16 17 18 19 20	THE WITNESS: They bill someone else.  BY MS. PARFITT:  Q Okay. So when you testified that J&J excuse me, when you testified that you had assistance with regard to the preparation of some of the materials that accompany your report, that was work that you contracted with Medical Service Affiliates to do, and they didn't bill you, they	14 15 16 17 18 19 20	A Well, let's look at the invoice if we want to. If it's on the top of that, then I might Q It's been blacked out, Dr. Diette. A So it's either a law firm or it's Johnson & Johnson. I don't know whether it's one or the other. MS. BROWN: Counsel, you're
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14 15 16 17 18 19 20 21	THE WITNESS: They bill someone else.  BY MS. PARFITT:  Q Okay. So when you testified that J&J excuse me, when you testified that you had assistance with regard to the preparation of some of the materials that accompany your report, that was work that you contracted with Medical Service Affiliates to do, and they didn't bill you, they	14 15 16 17 18 19 20 21 22	A Well, let's look at the invoice if we want to. If it's on the top of that, then I might Q It's been blacked out, Dr. Diette. A So it's either a law firm or it's Johnson & Johnson. I don't know whether it's one or the other. MS. BROWN: Counsel, you're

BY MS. PARFITT:  Q With I want to understand, for purpose of the expert report you prepared in this lifigation, I want you to tell me, if you will, every service that Medical Science Affiliates performed for you.  A I don't think I can give you a full list. I think that the -go ahead. Q No, no, please, go ahead. A All right. So I think the category of things that I told you about before are the kinds of the performance of the formation to you in the pass of the you keep asking the same thing, and if - my answer is I'm and the T min to - I'm to you we per training dike a couple of papers, I don't remember.  Page 163  think they did any for this. Q All right. So it's your testimony that in the talcum powder and ovarian cancer case, they did not do any research the peer-reviewed it in you are year the you whit the papers? A I don't - Hon the passing the you'd begovition		Page 162		Page 164
Q What I want to understand, for purpose of the expert report you prepared in this shall be severy service that Medical Science Affiliates performed for you.  A I don't think I can give you a full bit, I think that the - go ahead. Q No, no, please, go ahead. A All right. So I think the category of things that they that they did in this case. I I don't know if I mentioned like arranging like a phono call. Like if I was going to have a phono call, they would arrange that. Help with I already talked about defining editing reports and I can't think of right now. Q Okay. Did Medical Science Affiliates or research the scientific literature for you in preparation for some of the information contained in your expert report? A I don't I don't think they did any of that. I mean, they've they've done searches in the past on other other topics, but I don't  Page 163 think they did any for this. Q All right. So it's your testimony that in the talcum powder and ovarian cancer case, they did not do any research of the per-reviewed is about talcum powder and ovarian cancer case, they did not do any research of the per-reviewed is report and over talking about this particular matter as you're asking these questions or or- Q Well, that's a that's a great point. You got involved in talcum powder and ovarian talk about talcum powder and ovarian this particular matter as you're asking these questions or or- Q Well, that's a that's a great point. You got involved in talcum powder and ovarian talk about talcum powder and ovarian cancer because when you became engaged to work on talcum powder and varian cancer case, they did in this case.  A I talce they woo a better answer is Tm ont - I think it beptile to any iterative research for you. I all can't give the think of right now.  Q All right. So it's your testimony that in the talcum powder and ovarian cancer because as or whateve, hu we're talking about the over talking about the past of the	1	BY MS. PARFITT:	1	something else with the papers?
of the expert report you prepared in this  litigation, I want you to tell me, if you will,  every service that Medical Science Affiliates  performed for you.  A I don't think I can give you a full  list. I think that the —go ahead.  Q No, no, please, go ahead.  A All right. So I think the category of things that I wan be produced in things that I wan the plant because I — I find it easier to do it myself.  Q Whether it was helpful or not, my question is, did Medical Science Affiliates do any literature research for you in — on the topic of talcump moved reports and ovarian cancer?  I don't know if I mentioned like arranging like a phone call, they would arrange that. Help with — I already talked about editing — editing reports and proparation for some of the information contained preparation for some of the information contained preparation for some of the information contained in your expert report?  A I don't — I don't think they did any of that. I mean, they've — they've done hat at my request in the past. But not — not too much. I mean is causing the the past on the ready and the arranging like a large that they was better answer. I mean in — I think it sounds to me like you keep asking the search filiates and ovarian cancer?  A I can't give you a better answer. I mean I — I think it sounds to me like you keep asking the search filiates and ovarian cancer?  A I can't give you a better answer. I mean I — I think it sounds to me like you keep asking the search filiates are search the scientific filerature for you in — on the topic of talcump over pert pertor.  Page 163  think they did any for this.  Q Okay. Did Medical Science Affiliates  preparation for some of the information contained in preparation for some of the information contained in preparation for some of the information contained in the talcum powder and ovarian cancer — because think they did any for this.  Q All right. So it's your testimony that in the talcump owder and ovarian cancer — because I in the talcump owder and ovarian cancer — becaus	2		2	
4   A Yeah, and that's what I don't remember, 5   performed for you. 7   A I don't think I can give you a full 8   list. I think that the -go ahead. 9   Q No, no, please, go ahead. 9   Q No, no, please, go ahead. 11   A Al right. So I think the category of things that I told you about before are the kinds of things that I told you about before are the kinds of things that I told you about before are the kinds of things that I told you about before are the kinds of things that I they - that they did in this case. 12   I don't know if I meaninge that. Help with - I already talked about editing - editing reports and - I can't think of another service they did, but that's what I can think of right now. 19   Q Okay. Did Medical Science Affiliates reports and - I can't think of another service they did, but that's what I can think of right now. 19   Q Okay. Did Medical Science Affiliates reports are search the scientific literature for you in preparation for some of the information contained in your expert report? 20   research the scientific literature for you in preparation for some of the information contained in your expert report? 21   Q Okay. Did Medical Science Affiliates reports and - I can't think they did any of that. I mean, they've - they've done searches in the past on other - other topics, but I don't think they did any for this. 2   Q All right. So it's your testimony that in the taleum powder/ovarian cancer case, they did not do any research of the peer-reviewed in the past on other - other topics, but I don't have to think back with each - you know, each ease or whatever, but we're talking about this particular matter as you're asking these questions or	3		3	· · · · · · · · · · · · · · · · · · ·
severy service that Medical Science Affiliates performed for you.  A I don't think I can give you a full list. I think that the — go ahead.  O No, no, please, go ahead.  A All right. So I think the category of things that I they—that they did any of things that I they—that they did any of the past on other—other topics, but I don't  proparation for some of the information contained in the past on other—other topics, but I don't  the past on other—other topics, but I don't  Page 163  think they did any for this.  Q All right. So if sy our testimony that in the talcum powder roadvarian cancer case, they did not do any research of the peer-reviewed literature; is that correct?  A I is.  A I don't think that the —go ahead.  B (Whether it was helpful or not, my question is, did Medical Science Affiliates of any literature research for you in—on the topic of things that I was helpful or not, my question is, did Medical Science Affiliates of any literature research for you in—on the topic of things that I was helpful or not, my question is, did Medical Science Affiliates do any literature research for you in—on the topic of the past out a low mpowder advise a phone in the talcum powder and ovarian cancer.  A I can't give you a better answer. I most —on the origin of the your depart give you a better answer. I most —on the same I—in think is counted to make a phone in the talcum powder and ovarian cancer.  A I can't give you a better answer. I most —on the origin give a shift give a packed and it is already talked about editing —editing reports and for they did or not. They certainly didn't do the search, like I don't remove it frey did or not. They certainly didn't do the search, like I don't remove it frey did or not. They certainly didn't do the search, like I don't remove it frey did or not. They certainly didn't do the search, like I don't remove it is pour expert report.  A I don't home did Medical Science Affiliates and it is a particular matter as you't easient and you are porter.  A I don't thome would they de	4		4	
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	Page 166		Page 168
1	MS. BROWN: And, Counsel, here I'm going	1	Q Did you use for purposes of your expert
2	to interject, and to the extent your question	2	report any of the summaries that were that were
3	MS. PARFITT: Objection. Form.	3	conducted by Medical Science Affiliates that you
4	MS. BROWN: seeks to I'm	4	just spoke about?
5	instructing on privilege, which I'm allowed to do	5	A See, this is where I I don't know if
6	under the federal rules and under the	6	you're trying to confuse me or what, but
7	MS. PARFITT: If it's a privilege	7	Q No, I'm not.
8	issue	8	A Okay. So I just want to be clear,
9	MS. BROWN: let me do that.	9	because there aren't any summaries for this,
10	MS. PARFITT: it's certainly fine.	10	right.
11	MS. BROWN: Thanks. So my instruction	11	Q Okay.
12	here will be that, Doctor, you are not under the	12	A So and that's why I keep trying to
13	work-product privilege to disclose any	13	I just because there's a different answer for
14	correspondence you've had with MSA, unless it is	14	what what people have done in other matters and
15	something on which you rely for your opinions	15	what they've done in this matter. There aren't
16	here, and then of course, counsel is entitled to	16	any summaries that I'm aware of to to look at.
17	have that information.	17	Q All right. Did Medical Science
18	BY MS. PARFITT:	18	Affiliates help you write your expert report?
19	Q With that understanding, how do you	19	MS. BROWN: Objection to the form of the
20	answer the question?	20	question.
21	A Can you say it again because I think I	21	THE WITNESS: You know, "write" is a
22	lost it?	22	is a word that can mean a lot of things. They
23	Q Sure. Let me just have it read back to	23	helped me to to shape it, like to create the
24	you here.	24	the format for it and like edit out typos and
25	Has Medical Science Affiliates done any	25	things of that sort.
	Page 167		
-		1	
1	summaries of any type of information for you or	1	BY MS. PARFITT:
2	provided any information for you on the talcum	2 3	Q Okay. Well, that has it means a lot of things as well. So let me ask you
3	powder products and ovarian cancer cases?		•
4	MS. BROWN: Same instruction. If you're	4 5	MS. BROWN: Counsel, just ask the
5 6	relying on anything they've done, of course,	6	question.  MS. PARFITT: Counsel, I'm please.
7	please answer the question.  THE WITNESS: So if we're talking about	7	MS. BROWN: You can't editorialize like
8	cases because that's why I clarified before,	8	that. It's a question and an answer.
	· · · · · · · · · · · · · · · · · · ·	9	
9 10	we're not talking about this matter. We're talking about ever in any in any case?	10	BY MS. PARFITT:  Q Dr. Diette, what I would like to ask you
11	BY MS. PARFITT:	11	is, when you say they helped shape your report,
12	Q Ovarian cancer and talcum powder	12	what do you mean they helped shape your report?
13	products.	13	MS. BROWN: Objection.
14	A Oh, yeah. No, I understand the words.	14	THE WITNESS: What I just said I mean
15	I'm just trying to make sure whether we're talking	15	what I said after after that before.
16	about like this this matter that we're talking	16	BY MS. PARFITT:
17	about fike this this matter that we're taiking about only or or beyond that.	17	Q Is every word in your expert report that
18	Q Has has beyond that.	18	you have there in front of you a word that you put
19	A So I'm going to say probably they have.	19	in it?
20	That if there are cases where there were like	20	MS. BROWN: Objection to the form.
21	medical records, for example, although I don't	21	THE WITNESS: Well, I don't know. I
22	think I've gotten any medical records, but they	22	mean, there's there's quotes from people,
23	would have provided a summary. If there were	23	right, so that those aren't my words, for example.
24	deposition transcripts in those other cases, they	24	BY MS. PARFITT:
25	might well have have done that.	25	Q Well, you know, I'm glad you brought
_	G		, j e ae, 1 m Biad j e a e reagin

43 (Pages 166 to 169)

that up. That's a good question.  A Yeah.  Q Are the opinions and the writings  contained in that report words that you selected?  A Oh, for sure. I mean like the opinions  and my - my summaries of things and is that what we're talking about?  Q No. No.  A We're not? All right.  Q The report is about let's see how  Many pages it's about 51 pages long, and the question I have, with the exception of quotes from other people, Dr. Diette, is every word in this report a word you chose to put in the report?  MS. BROWN: Objection to the form.  THE WITNESS: For sure, yes. Although like some of the words, for example, I think might come from one of those affidavits that we were and then pulled into this.  BY MS. PARFITT:  Q Okay. Well, then when you say "Medical Science Affiliates helped shape," I'm trying to get an understanding, what do you mean "shape"?  A It would look like a disaster if I did across, to have, you know, references look okay.  That I'm not good at. So the fact that this, in my view, looks like a professional product, that's what they that's what t	he of your ges?
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11 Q Okay. There are multiple footnotes in 11 report to anyone?	
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your report to testimony of various experts that 12 A I don't I don't do that.	
were retained by the plaintiff. 13 Q You don't dictate. Okay.	
14 A Yeah. 14 A No.	
Q Who prepared those footnotes? 15 Q Did you spend time on the phone w	th
MS. BROWN: Objection to the form. 16 anyone at MSA and discuss what your yo	
17 THE WITNESS: Staff somewhere, but 17 should look like?	
18 BY MS. PARFITT: 18 MS. BROWN: And again, I'm going	
19 Q I'm sorry. 19 instruct on work product, that you not revea	ur report to
20 A Staff. 20 substance of any discussions you had regard	to the
21 Q Staff? 21 drafts of this report. Whether or not there w	to the ing
22 A Yes. 22 conversation is an appropriate question to a	to the ing as a
Q What staff? 23 THE WITNESS: Sure.	to the ing as a
24 A I don't know which staff did it, but I 24 BY MS. PARFITT:	to the ing as a
25 mean like the if you say who prepared the 25 Q You did?	to the ing as a

	Page 174		Page 176
1	A Yes.	1	at MSA to help you get your report in order?
2	Q So you had a conversation	2	MS. BROWN: Objection to the form,
3	A Yes.	3	misstates the testimony.
4	Q about the substance of your report,	4	THE WITNESS: I don't recall the amount
5	correct?	5	of time. I mean whatever it took. Like some of
6	MS. BROWN: Objection to the form.	6	it might be like a two-minute conversation to say
7	THE WITNESS: Oh, no, you just you	7	like, you know, I want to move a section down or
8	said something else before that. What was the	8	something. Or, you know, Can you proofread that
9	question before?	9	particular paragraph and look for typos? And
10	MS. BROWN: Discuss what your report	10	things of that sort.
11	should look like.	11	BY MS. PARFITT:
12	THE WITNESS: Yeah, that's different.	12	Q Did any of the folks at MSA make any
13	BY MS. PARFITT:	13	suggestions with regard to the scientific or
14	Q Okay.	14	medical content of your report?
15	A You changed it to "substance." But I	15	MS. BROWN: Objection. Instruct not to
16	mean what it should look like is what I'm talking	16	answer on work product. You can discuss you
17	about. It was it should look good, right? And	17	can answer the question of whether you had any
18	so there should be like, you know, bold headings	18	conversations, the substance of which is
19	and there should be spaces where they belong.	19	privileged, and I'll instruct you not to answer.
20	Q What's the name of the contact person	20	MS. PARFITT: MSA is a third-party
21	you interfaced with at MSA?	21	contractor from what I'm understanding.
22	A My main one is Maddie Petta	22	MS. BROWN: No different than if he was
23	Pettenati.	23	working with a secretary to format this.
24	Q Okay. And how long have you worked with	24	Conversations about drafts of the report are
	Q 0-111/3 1 -110 11 0 11 0 1 0 1 0 1 0 1 1 0 1 1 1 1		Contractions access arange of the report are
25	Maddie Pettenati?	25	privileged and will not be discussed.
		25	
25	Page 175		Page 177
25	Page 175 A A couple of years.	1	Page 177 BY MS. PARFITT:
25 1 2	Page 175  A A couple of years.  Q Okay. Do you work with anyone else over	1 2	Page 177 BY MS. PARFITT: Q Doctor, if you can answer the question.
25 1 2 3	Page 175  A A couple of years.  Q Okay. Do you work with anyone else over at MSA to help you with your reports?	1 2 3	Page 177  BY MS. PARFITT:  Q Doctor, if you can answer the question.  A Can you say it again? I'm sorry.
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45 (Pages 174 to 177)

	Page 178		Page 180
1	add \$85 when they bill somebody for my time.	1	and basically an amount. I don't have
2	Q Who "they"?	2	A Like it
3	A MSA.	3	Q it's been blacked out.
4	Q "They," MSA?	4	A It doesn't matter. I can still
5	A Yeah.	5	MS. BROWN: It's been redacted for work
6	Q All right. So that I get it straight,	6	product.
7	you charge 400 \$400 for your time, correct?	7	THE WITNESS: I mean I can help you
8	A Correct.	8	understand it if you want.
9	Q And then your understanding is MSA	9	BY MS. PARFITT:
10	charges an additional \$85 to someone for their	10	Q All I really want to understand and get
11	assistance for you, correct?	11	a better understanding, Dr. Diette, is the types
12	MS. BROWN: Objection to the form, calls	12	of services that MSA provided you in order to
13	for speculation.	13	file this prepare this report.
14	THE WITNESS: So it's I don't know	14	A Yeah, I I listed those.
15	I don't know how they break it down, because they	15	Q Okay. Do they help you with all of your
16	bill for different things, like they bill for	16	expert reports?
17	photocopying, they bill for some administrative	17	A In what?
18	tasks separately. Whatever it is, it's their	18	Q Does MSA provide any type of service in
19	business model, and they they add that amount	19	any and all expert reports that you prepare in the
20	to the hourly rate.	20	context of litigation?
21	BY MS. PARFITT:	21	A No.
22	Q How much did Medical Science bill for	22	Q Okay. Do you have another go-to service
23	their work, do you know?	23	to help you with the preparation of your expert
24	MS. BROWN: Objection. Calls for	24	services?
25	speculation.	25	MS. BROWN: Objection to form.
	Page 179		Page 181
1	THE WITNESS: You can tell if we look at	1	THE WITNESS: No. I do stuff on my own
2	the the invoices.	2	as well.
3	BY MS. PARFITT:	3	BY MS. PARFITT:
4	Q Okay. They would bill the same number	4	Q All right. So there are cases where
5	of well, let me ask for a clarification. Not	5	you've done the work by yourself, and there are
6	all your work was done in conjunction with the	6	cases like this particular case where you engage
7	assistance of Medical Science Affiliates, correct?	7	the services of MSA, correct?
8	MS. BROWN: Objection to the form.	8	A That is
9	THE WITNESS: I mostly sat by myself.	9	MS. BROWN: Objection to the form.
10	Yeah.	10	THE WITNESS: correct.
11	BY MS. PARFITT:	11	BY MS. PARFITT:
12	Q Okay. So the invoices that I have for	12	Q Okay. And did MSA edit any of your
13	you would not necessarily reflect all of the work	13	any of your did MSA edit your expert report?
14	that Medical Science Affiliates afforded you,	14	A Yeah.
15	correct?	15	Q Okay. What kind of edits did they make?
16	A That's incorrect.	16	A Well, all sorts. Like I asked them to
17	MS. BROWN: Objection to the form.	17	look for typos, for example.
18	BY MS. PARFITT:	18	Q Right.
19	Q Okay.	19	A I just happen to be open to page 30 and
20	A I mean that's what I was trying to offer	20	31, and where you see that the there's like
	you earlier is to try to understand the the	21	bulleted sections, when I wrote that, it was just
21		22	one long impenetrable paragraph, and so they were
21 22	bills. Because also when you add that comment	1	
21 22 23	about the amount of money in total, it wasn't all	23	nice enough to sort of break it into some chunks
21 22		1	

	Page 182		Page 184
1	before, but did MSA ever suggest any new sentences	1	Q And I'm not concerned about the format.
2	or study that you didn't previously insert in your	2	What I'm concerned about is the substance,
3	paper?	3	Dr. Diette, as you can appreciate.
4	A I doubt a new study. It could be I	4	MS. BROWN: Objection.
5	mean we worked we worked pretty hard to make	5	BY MS. PARFITT:
6	sure that I have the full list of studies, you	6	Q And so what I'm trying to to get some
7	know, acknowledged, and so if there was something	7	clarity here is that, other than perhaps providing
8	I left off I mean I don't remember this	8	you a study that you may have omitted from your
9	specifically for this, but that would be a normal	9	report, is there anything else that falls more in
10	practice, right, like which is to say, you know,	10	the substantive area that they provided and
11	Oh, I saw in your list of papers that there's a	11	offered for you?
12	Smith paper, should that be on here? Not them	12	A I I think I've answered as best I
13	going out and saying, Oh, I found a Smith paper,	13	can.
14	would you like that on there?	14	Q Well, why don't we let's talk about
15	Q But they might looked at yours and say,	15	your contact with J&J. When did they first reach
16	You you missed a study. Fair?	16	out to you to talk with you about being an expert
17	A Oh, sure.	17	to defend them in these lawsuits?
18	MS. BROWN: Objection to the form.	18	MS. BROWN: Objection to the form of the
19	THE WITNESS: Yeah.	19	question.
20	BY MS. PARFITT:	20	THE WITNESS: So they never asked me to
21	Q Okay. And they might look at your	21	defend them. They they asked me to evaluate
22	report and say, You missed	22	the epidemiologic literature.
23	I think what I'm getting at, Dr. Diette,	23	And just to be clear, because it seemed
24	you described their efforts as generally	24	like it was tripping us up before trying to talk
25	editorial. Is that fair?	25	about this, when I talk about J&J, it's lawyers
	Page 183		Daga 10F
			Page 185
1		1	
1 2	MS. BROWN: Objection to the form. THE WITNESS: I would say administrative	1 2	that are working with J&J as opposed to somebody
	MS. BROWN: Objection to the form.		
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2 3 4 5 6	MS. BROWN: Objection to the form.  THE WITNESS: I would say administrative and editorial.  BY MS. PARFITT:  Q Okay. So we can agree that it's both	2 3 4 5 6	that are working with J&J as opposed to somebody from J&J per se. And so I'll leave it to you guys to sort out what that what that means.  BY MS. PARFITT:  Q Fair enough.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. BROWN: Objection to the form. THE WITNESS: I would say administrative and editorial. BY MS. PARFITT: Q Okay. So we can agree that it's both administrative and editorial? MS. BROWN: Objection to the form. THE WITNESS: Correct. BY MS. PARFITT: Q And as I appreciate, in addition to perhaps providing you with a study or two that or three, however number, that you might have omitted, is there anything substantive like that that they did for you for purposes of your expert report? A I insist that they don't. I tell them that I don't want any intellectual input into the to the stuff that we're working on. Like I don't want their I don't even know if they have opinions, but I don't want their opinions. I literally want this to look like a professional	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	that are working with J&J as opposed to somebody from J&J per se. And so I'll leave it to you guys to sort out what that what that means. BY MS. PARFITT:  Q Fair enough.  A But but the first time would have been a lawyer back in 2017 who asked if I would be interested in reviewing the epidemiologic literature.  Q Who was that lawyer?  A Jonathan Cooper.  Q Okay. Now, at the time that Jonathan or Jonathan Cooper contacted you, did you were you working with MSA?  A Obviously, because I said ten years, and, you know, this was 2017.  Q Okay. Did you share with Jonathan Cooper that you worked with this MSA company to help you prepare your expert reports?  A He knew about it already, because I think the reason he reached out to me is because

	Page 186		Page 188
1	done, when he let me explore that a little bit.	1	Q Okay. Have they ever listed you on some
2	When he called you, did you tell him	2	type of website as a consultant for legal
3	that you had previously worked with MSA to help	3	purposes?
4	you with your expert reports?	4	A Well, I see
5	A I didn't have to.	5	MS. BROWN: Objection to the form,
6	Q He knew that.	6	calls for speculation.
7	A Yes.	7	THE WITNESS: Mr. Finch is here and
8	Q Okay. How would Mr. Cooper have known	8	he
9	that you worked with MSA before?	9	THE REPORTER: Excuse me.
10	MS. BROWN: Objection to the form, calls	10	THE WITNESS: Oh, sorry.
11	for speculation.	11	MS. BROWN: Objection to the form, call
12	MR. LOCKE: Objection.	12	for speculation. Thank you.
13	BY MS. PARFITT:	13	THE WITNESS: Mr. Finch flashed
14	Q If you know. Seems like you know.	14	something up at a trial to suggest that they had,
15	A Oh, I do. We had he and I had worked	15	but that wasn't an advertisement for me. It was a
16	together on other cases.	16	list of somebody who had credentials that were
17	Q Okay. What other cases did you work	17	similar to mine.
18	with Mr. Cooper on?	18	BY MS. PARFITT:
19	A They were asbestos-related cases with	19	Q Okay. Well, my question is, have are
20	plastic or phenolics, like electrical equipment.	20	you aware of whether or not Medical Science
21	Q Okay. And in those cases that you	21	Affiliates has ever advertised your name out in
22	worked with Jonathan on or Mr. Cooper on, did	22	the the community as someone
23	you utilize the services of MSA as well to help	23	MS. BROWN: Same objection
24	you prepare your expert report in those cases?	24	BY MS. PARFITT:
25	A I did.	25	Q who was a specialist in pulmonology
	Page 187		Page 189
1	Q Okay. Has MSA reached out to you and	1	medicine?
2	engaged or asked if you would engage in assisting	2	MS. BROWN: Same objection.
3	them on any other projects currently?	3	THE WITNESS: I'm not aware that they
4	A What do you mean by "currently"?	4	advertise.
5	Q Well, are you working with MSA on any	5	BY MS. PARFITT:
6	other projects other than the talcum powder	6	Q Okay. So are there times that Medical
7	products and ovarian cancer?	7	Science Affiliates reaches out to you and says,
8	A Yes.	8	Dr. Diette, we want you to do a medical a
9	Q What projects?	9	scientific review for us on a topic?
10	MS. BROWN: And again, Doctor, to the	10	A Never.
11	extent that a confidentiality agreement doesn't	11	Q Okay. They've never done that. You've
12	prevent you from disclosing other work that you're	12	never provided that service for them.
13	doing, you can answer the question.	13	A They they don't ask me to do work for
14	THE WITNESS: Some cases that relate to	14	them.
15	asbestos and other chemical-related cases.	15	Q Okay. Do their clients ask you to do
16	BY MS. PARFITT:	16	work for them?
17	Q Okay. Was there a time when you,	17	A Of course, that's where we started,
18	instead of receiving services from MSA, you	18	right, from ten years ago.
19	provided services to MSA as an affiliate expert?	19	Q Right. And that's what I'm trying to
20	MS. BROWN: Objection to the form of the	20	figure out.
21	question.	21	MS. BROWN: Let him finish. I don't
22	THE WITNESS: I know they have that word	22	think he was done.
23	"affiliate" in their name. I don't know what that	23	THE WITNESS: No, that was that was
24	means. But I don't provide services to them.	24	the description of what I was saying, like how
25	BY MS. PARFITT:	25	the the first time that I met them was that
20	~ 1140, 1140, 111.	23	and the first time that I met them was that
		1	

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	Page 190		Page 192
1	they there was some, you know, group that	1	Q So you never work for MSA; you always
2	wanted an epidemiologic review, and they were	2	work for a corporate client?
3	trying to figure out if there were local	3	MR. LOCKE: Objection.
4	epidemiologists that could take on a task like	4	MS. BROWN: Objection to the form of the
5	that, and so that's the way it worked.	5	question.
6	BY MS. PARFITT:	6	THE WITNESS: So I've never worked for
7	Q Okay. So I now get	7	MSA.
8	MS. BROWN: He is not done.	8	BY MS. PARFITT:
9	BY MS. PARFITT:	9	Q Who pays your bills? Law firms?
10	Q Are you done, Doctor? I thought you	10	MS. BROWN: Objection to the form.
11	were.	11	THE WITNESS: So
12	A I'll be done.	12	MS. BROWN: What bills? What are you
13	Q Okay. So if I appreciate this	13	talking about?
14	structure, so we can move on, a client, some	14	BY MS. PARFITT:
15	company can reach out to Medical Science	15	Q Who pays your bills for doing services
16	Affiliates and say, We need some work done and	16	at the request of MSA?
17	research done on a particular area. Will you do	17	MS. BROWN: Objection to the form.
18	that for me?	18	BY MS. PARFITT:
19	Medical Science Affiliates will say,	19	Q Anybody?
20	Yes, we can. And then Medical Science Affiliates	20	MS. BROWN: Objection. Can we let's
21	reaches out to people like you?	21	have one question and let him answer.
22	MS. BROWN: Objection to the form.	22	Go ahead.
23	THE WITNESS: So I don't know I don't	23	BY MS. PARFITT:
24	know when they say, Yes, we can. Like I don't	24	Q And I'll tell you the reason I'm asking,
25	know, for example like their I don't know	25	Dr. Diette.
	Page 191		Page 193
1	what their size is, but they may say, Yes, we can,	1	MS. BROWN: No, no, no, no. You ask the
2	and just do it themselves. Right. They have	2	question, he answers. We don't need to know why
3	other people that I don't work with that work	3	you're asking the question.
4	there.		
-		4	MS. PARFITT: Excuse me.
5	I'm just saying, like you're asking the	5	MS. PARFITT: Excuse me. MS. BROWN: It's improper. You're not
5 6	I'm just saying, like you're asking the question, so it's like so if somebody calls		
		5	MS. BROWN: It's improper. You're not
6	question, so it's like so if somebody calls	5 6	MS. BROWN: It's improper. You're not going to give a speech, Counsel.
6 7	question, so it's like so if somebody calls them and says, Can you do this work? They may	5 6 7	MS. BROWN: It's improper. You're not going to give a speech, Counsel. BY MS. PARFITT:
6 7 8	question, so it's like so if somebody calls them and says, Can you do this work? They may well say, Yes, we can do it. They may or may not	5 6 7 8	MS. BROWN: It's improper. You're not going to give a speech, Counsel.  BY MS. PARFITT:  Q Dr. Diette, we has there ever been a chance or an opportunity where you have reached out to MSA on your own, and say, A client that
6 7 8 9	question, so it's like so if somebody calls them and says, Can you do this work? They may well say, Yes, we can do it. They may or may not need a content expert or methodologic expert to do	5 6 7 8 9	MS. BROWN: It's improper. You're not going to give a speech, Counsel.  BY MS. PARFITT:  Q Dr. Diette, we has there ever been a chance or an opportunity where you have reached
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1	MS. BROWN: Objection to the form.	1	conflicts checks?
2	THE WITNESS: Something like that, yeah.	2	MS. BROWN: Objection. Speculation.
3	BY MS. PARFITT:	3	Engaged by who?
4	Q Okay. That's one scenario.	4	BY MS. PARFITT:
5	Another scenario is when a corporate	5	Q When you're engaged by a client, who
6	client, for instance, engages the services of MSA	6	does the conflict
7	to do a project and a particular expertise is	7	MS. BROWN: Same
8	needed, and MSA then reaches out to folks like	8	BY MS. PARFITT:
9	yourself or folks in other medical specialties.	9	Q conflicts checks for you?
10	Fair?	10	MS. BROWN: Same objection.
11	MS. BROWN: Objection. Speculation.	11	THE WITNESS: I don't know that anybody
12	THE WITNESS: So I'm not a lawyer,	12	does conflicts checks. I mean if there is
13	right. So I'm trying to listen carefully to the	13	somebody, I'm not aware of who that is. If it
14	words that you're using, and when you say they	14	comes up, people will ask me sometimes if I have a
15	reach out and they retain MSA, I I actually	15	conflict of interest. Sometimes I'll see a
16	don't know if that's actually what happens, right.	16	complaint, you know, and be asked to look at, you
17	So I gave you an example that	17	know, the names on the complaint.
18	BY MS. PARFITT:	18	It all depends, but I I don't even
19	Q Okay.	19	know if I know what a conflict checks is, I mean
20	A they might retain MSA for their own	20	if that's a technical term. It's only been
21	purposes, and nobody else gets involved. If like,	21	it's only been done the way I'm describing, which
22	for example, in this case when Jonathan Cooper	22	somebody will say to me like, you know, Do you
23	reached out, he wanted to work with me, and MSA	23	have any conflict of interest?
24	provided the support services for me to get that	24	BY MS. PARFITT:
25	work done. So I I have no idea whether he	25	Q Okay. You prepared two affidavits that
23	work done. So I I have no idea whether he	25	Q Okay. Tou prepared two arridavits that
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1	Page 195 retained MSA per se. I mean that's that's	1	Page 197 I'm aware of, one in the Ingham case and one in
1 2	Page 195 retained MSA per se. I mean that's that's something for lawyers to kind of sort through.	1 2	Page 197 I'm aware of, one in the Ingham case and one in the Forrest. Do you recall doing that back in
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	Page 198		Page 200
1	you know, the input for that was stuff I was	1	products and ovarian cancer.
2	already, you know, reading and interpreting	2	And the question I have is, in any
3	otherwise.	3	context, when the topic of interest is talcum
4	BY MS. PARFITT:	4	powder products and ovarian cancer, have you ever
5	Q All right. How much did you charge for	5	been asked by MSA to do any work that's
6	the Forrest report?	6	non-pulmonary, other than the ovarian cancer
7	MS. BROWN: Objection to the form.	7	cases?
8	THE WITNESS: The same same answer.	8	A Related
9	I don't know. And in fact, the Forrest report, if	9	MR. LOCKE: Objection.
10	it came second, probably not very much because I	10	THE WITNESS: Related to talcum powder?
11	think it's mostly derivative from the first. I	11	BY MS. PARFITT:
12	mean I try I'm not trying to just, you know,	12	Q Related to anything.
13	create work to create it. Like if there's	13	A Well, wait a minute. No, because so,
14	something I that I like the way it reads, I try	14	first of all, you said has MSA asked me to do it.
15	to use it again.	15	Like they don't ask me to do stuff. Like they
16	BY MS. PARFITT:	16	it's the relationship we described before is
17	Q Okay. Are you aware, having actually	17	what it is. So if it's more general about are
18	prepared both of those affidavits, they are	18	there other cases
19	virtually the same affidavit? Would that surprise	19	O Yeah.
20	you?	20	A and when you say non-pulmonary, you
21	MS. BROWN: Objection to the form.	21	know, there are cases I've been involved in that
22	THE WITNESS: I hope they are. I mean	22	have nothing do with talcum powder that are
23	that that was the intent.	23	non-pulmonary.
24	BY MS. PARFITT:	24	So I'm just trying to figure out,
25	Q Okay. Other than the ovarian cancer/	25	there's a lot of different angles to what to
	Page 199		Page 201
1	talcum powder cases, have you been engaged by	1	what you're asking.
2	anyone else for opinions on a non-pulmonary issue?	2	Q Sure.
3	MS. BROWN: Objection to the form.	3	A Are you talking about talcum powder
4	THE WITNESS: Related to?	4	cases that are related to something other than
5	BY MS. PARFITT:	5	ovarian cancer, and something other than a
6	Q Your work with MSA.	6	pulmonary
7	A No, but you said it sounded like	7	Q I'll simplify it. Have you ever
8	there's something missing from the question.	8	prepared a report in a let me do it this way.
9	Q Sure. Let me let me ask it again.	9	Talcum powder products and ovarian
10	Okay.	10	cancer have nothing to do with pulmonary medicine,
11	Other than this case involving ovarian	11	correct?
12	cancer and talcum powder products, have you been	12	MS. BROWN: Objection to the form. Are
13	asked and or requested by anyone for your	13	we abandoning inhalation as a theory of
		14	MC DADELET NA .
14	opinions on a topic that was something other than	1	MS. PARFITT: No, we're not, no.
15	non-pulmonary?	15	MS. BROWN: Okay.
	non-pulmonary?  MS. BROWN: Objection. Do you mean	15 16	MS. BROWN: Okay. THE WITNESS: Then no. I mean, no,
15 16 17	non-pulmonary?  MS. BROWN: Objection. Do you mean MS. PARFITT: That was non-pulmonary.	15	MS. BROWN: Okay.  THE WITNESS: Then no. I mean, no, meaning that if that's a theory, then that
15 16 17 18	non-pulmonary?  MS. BROWN: Objection. Do you mean MS. PARFITT: That was non-pulmonary. MS. BROWN: to exclude Ingham and the	15 16 17 18	MS. BROWN: Okay.  THE WITNESS: Then no. I mean, no, meaning that if that's a theory, then that certainly has something to do with pulmonary
15 16 17	non-pulmonary?  MS. BROWN: Objection. Do you mean MS. PARFITT: That was non-pulmonary. MS. BROWN: to exclude Ingham and the other? When you say "this case," do you mean just	15 16 17	MS. BROWN: Okay.  THE WITNESS: Then no. I mean, no, meaning that if that's a theory, then that
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15 16 17 18 19 20	non-pulmonary?  MS. BROWN: Objection. Do you mean MS. PARFITT: That was non-pulmonary. MS. BROWN: to exclude Ingham and the other? When you say "this case," do you mean just the MDL?	15 16 17 18 19 20	MS. BROWN: Okay.  THE WITNESS: Then no. I mean, no, meaning that if that's a theory, then that certainly has something to do with pulmonary medicine.  BY MS. PARFITT:
15 16 17 18 19 20 21	non-pulmonary?  MS. BROWN: Objection. Do you mean MS. PARFITT: That was non-pulmonary. MS. BROWN: to exclude Ingham and the other? When you say "this case," do you mean just the MDL? MS. PARFITT: Yeah.	15 16 17 18 19 20 21	MS. BROWN: Okay.  THE WITNESS: Then no. I mean, no, meaning that if that's a theory, then that certainly has something to do with pulmonary medicine.  BY MS. PARFITT:  Q Okay. And I think what I'm really
15 16 17 18 19 20 21 22	non-pulmonary?  MS. BROWN: Objection. Do you mean MS. PARFITT: That was non-pulmonary. MS. BROWN: to exclude Ingham and the other? When you say "this case," do you mean just the MDL? MS. PARFITT: Yeah. BY MS. PARFITT:	15 16 17 18 19 20 21 22	MS. BROWN: Okay.  THE WITNESS: Then no. I mean, no, meaning that if that's a theory, then that certainly has something to do with pulmonary medicine.  BY MS. PARFITT:  Q Okay. And I think what I'm really driving at is, it looks as though your focus for

	Page 202		Page 204
1	MR. LOCKE: Objection.	1	anything
2	THE WITNESS: My focus	2	Q Do you want to take
3	BY MS. PARFITT:	3	A No, I'm just wondering. Not
4	Q Focus and research	4	necessarily, but if it's
5	MS. BROWN: Objection.	5	MS. MILLER: This would be a good time
6	BY MS. PARFITT:	6	for lunch.
7	Q for preparation of expert legal	7	THE WITNESS: Yeah, that's what I'm
8	reports.	8	wondering, just if it's going to be
9	MS. BROWN: Objection to the form.	9	MS. BROWN: Yeah, it's up to you. If
10	THE WITNESS: I I'm either not	10	you want to break, counsel will give you a break.
11	hearing you well or I think things are getting	11	MS. PARFITT: Whatever you want to do.
12	jumbled.	12	Do you want to take a break now?
13	BY MS. PARFITT:	13	THE WITNESS: It would be nice to to
14	Q Okay.	14	get a snack, and
15	A And I	15	MS. PARFITT: You want to take a half
16	Q Probably the the latter.	16	hour and grab
17	A No, and I apologize.	17	THE WITNESS: Would that be okay?
18	Q It's probably me.	18	MS. PARFITT: That's totally fine, yep.
19	A I'm not trying to give you a hard time.	19	THE VIDEOGRAPHER: The time is 12:08
20	I just mean that what I what I heard earlier	20	p.m., and we are going off the record.
21	is am I working on something with talcum powder	21	(Lunch recess.)
22	other than ovarian cancer or other than ovarian	22	THE VIDEOGRAPHER: The time is 12:43
23	cancer and something that isn't part of the lung?	23	p.m., and we're back on the record.
24	Is that it?	24	BY MS. PARFITT:
25	Q Are you preparing expert reports on a	25	Q Good afternoon, Dr. Diette.
	D 002		D 005
_	Page 203		Page 205
1	topic area other than talcum powder products and	1	A Good afternoon.
2	ovarian cancer currently?	2	Q All right, Dr. Diette, I'd like to focus
3	MS. BROWN: Objection. He's not	3	for a little bit about your actually your
4	answering questions about reports that have not	4	expert report and hopefully get to your opinions
5	been served in cases	5	here soon.
6	MS. PARFITT: Understood.	6	It's fair to say that this report is
7	MS. BROWN: where he's not a	7	this expert report is not a report that you
8	disclosed expert.	8	prepared in the ordinary course of your activities
9	THE WITNESS: You mean in my	9	as a pulmonary medicine at Johns Hopkins?
10	professional life in general?	10	MS. BROWN: Objection to the form.
11 12	BY MS. PARFITT:	11	THE WITNESS: That's correct.
	Q Correct.	12	BY MS. PARFITT:
13	A Yes.	13	Q Okay. And are all the opinions which
14	Q Okay. What other areas?	14	you will be sharing with us today, and eventually
15 16	A Well, that's what we talked about	15	the court and a jury, set forth in your your
16 17	before, right. So there was asbestos, there's	16	expert report?
17	some chemicals, probably like mold and dampness.	17	MS. BROWN: Form.
18 19	There's malpractice cases. I mean a whole variety	18	THE WITNESS: I hope so. I mean, it's there may be like like smaller opinions
20	of different things.	19 20	•
21	Q Okay. All right. I want to come to		that are underpinnings that I didn't capture, but
21 22	where I want to go is your your actual report.	21	I mean the fundamental opinions should be there.
	I want you to take me through I'll ask you some	22 23	And assuming nothing different comes out when you're asking me about it today, I guess the only
			voilte asking the about it today. I guess the only
23	questions about the process that you went through		
	questions about the process that you went through in actually putting this report together.  A And I don't want to overbreak or	24 25	other thing I'd say is that I don't think that I've seen all of the the testimony yet in this

Gregory B. Diette, M.D.

	Page 206		Page 208
1	case. So I don't know whether that's going to,	1	to say that that is your signature on the on
2	you know, spur some other thought, you know, from	2	the front page, Gregory Diette?
3	the other other experts who are testifying, but	3	A Yes, it is.
4	aside from that, then this should otherwise be	4	Q And you completed that on February 25th,
5	complete.	5	2019, correct?
6	BY MS. PARFITT:	6	A Exactly right.
7	Q And obviously if you see something,	7	Q Okay. And it would also is it also
8	testimony that causes you to change your opinions,	8	fair to say that the opinions contained in this
9	you will let me know, correct?	9	report are not the opinions of Johns Hopkins
10	MS. BROWN: Form.	10	University?
11	THE WITNESS: I will.	11	A Not as far as I know. I mean they're
12	BY MS. PARFITT:	12	literally just mine.
13	Q All right. Dr. Diette, on the front of	13	Q Have you shared these opinions with any
14	your report it says "Expert Report of Gregory	14	of the other members of the Johns Hopkins
15	Diette, MD, MHS, For General Causation Daubert	15	community?
16	Hearing." Did you write that?	16	A No.
17	A Not this page, no.	17	Q All right. Did you run the opinions
18	Q All right. Who wrote that?	18	that you have by any of the staff or your
19	MS. BROWN: Objection to the form.	19	superiors at Johns Hopkins?
20	THE WITNESS: I I don't know	20	MS. BROWN: Objection to the form.
21	literally. I think this came from the law firm as	21	THE WITNESS: No.
22	a cover page for me to to sign.	22	BY MS. PARFITT:
23	BY MS. PARFITT:	23	Q Okay. Aside from this expert report and
24	Q You've testified both in general	24	the opinions retained herein, have you shared your
25	causation case as a general causation witness	25	opinions with anyone else outside of the Johns
25	causation case as a general causation witness  Page 207	25	-
25	Page 207	25 1	opinions with anyone else outside of the Johns
	<del>-</del>		opinions with anyone else outside of the Johns  Page 209
1	Page 207 and as well as a specific causation witness,	1	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific
1 2	Page 207 and as well as a specific causation witness, correct?	1 2	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?
1 2 3	Page 207 and as well as a specific causation witness, correct?  A Generally speaking, like in legal cases?	1 2 3	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?  MS. BROWN: Objection to the form.
1 2 3 4	Page 207 and as well as a specific causation witness, correct?  A Generally speaking, like in legal cases? Q Correct.	1 2 3 4	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?  MS. BROWN: Objection to the form.  THE WITNESS: No. You mean other than
1 2 3 4 5	Page 207  and as well as a specific causation witness, correct?  A Generally speaking, like in legal cases? Q Correct. A Yes, I have.	1 2 3 4 5	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?  MS. BROWN: Objection to the form.  THE WITNESS: No. You mean other than the lawyers and
1 2 3 4 5	Page 207  and as well as a specific causation witness, correct?  A Generally speaking, like in legal cases? Q Correct. A Yes, I have. Q All right. So you understand the	1 2 3 4 5 6	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?  MS. BROWN: Objection to the form.  THE WITNESS: No. You mean other than the lawyers and BY MS. PARFITT:  Q Correct, other than your lawyers.
1 2 3 4 5 6 7	Page 207  and as well as a specific causation witness, correct?  A Generally speaking, like in legal cases? Q Correct. A Yes, I have. Q All right. So you understand the difference.	1 2 3 4 5 6 7	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?  MS. BROWN: Objection to the form.  THE WITNESS: No. You mean other than the lawyers and BY MS. PARFITT:
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1 2 3 4 5 6 7 8	and as well as a specific causation witness, correct?  A Generally speaking, like in legal cases? Q Correct. A Yes, I have. Q All right. So you understand the difference. A I hope so, yeah. Q Okay. Have you actually testified in an asbestos/meso mesothelioma case on giving	1 2 3 4 5 6 7 8	opinions with anyone else outside of the Johns  Page 209  Hopkins community, regulatory or scientific bodies?  MS. BROWN: Objection to the form.  THE WITNESS: No. You mean other than the lawyers and BY MS. PARFITT:  Q Correct, other than your lawyers.  A Oh, yeah, yeah, yeah.  MS. BROWN: Objection to the form.  We're not his lawyers.
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53 (Pages 206 to 209)

	Page 210		Page 212
1	front of you?	1	Q Okay. And if you would turn be so
2	A I do. Thank you.	2	kind to turn to the last page of the report,
3	Q Okay. Is it fair to say that your	3	page 51.
4	report contains the bases for your opinions as	4	A Okay.
5	well?	5	Q And again, if you would read the first
6	A Yes.	6	paragraph.
7	Q All right. And is it fair the do you	7	A At the
8	know whether or not this report has answered all	8	Q And we'll go ahead and put that up on
9	the questions that J&J asked you to answer for	9	the ELMO.
10	them?	10	A Under "Conclusion" or the
11	MS. BROWN: Objection. Lacks	11	Q Under the Conclusion, if you will.
12	foundation.	12	A Yep. The whole thing?
13	THE WITNESS: Well, I think there's only	13	Q Just that just that first
14	one question, right?	14	paragraph or first sentence.
15	BY MS. PARFITT:	15	A First sentence. Oh, okay. Yep.
16	Q And what was that question?	16	"It is my opinion, based on my
17	MS. BROWN: Wait. Let him finish.	17	qualifications and my extensive review of the
18	BY MS. PARFITT:	18	available epidemiology studies and scientific
19	Q What was that question?	19	literature, that there is not sufficient evidence
20	A I'm sorry. So the question was was	20	to conclude that there is a causal relationship
21	really about whether or not the what does the	21	between perineal talcum powder exposure and
22	epidemiologic evidence say about the relationship	22	ovarian cancer."
23	between talcum powder and ovarian cancer.	23	Q Okay. And I know you have much to say
24	Q All right. So let's turn to your	24	about that, but that is basically the the
25	report, page 2, and I believe	25	general opinion that you're going to be sharing,
	Page 211		Page 213
	- 3 -		rage 213
1	MS. PARFITT: And we'll put it up on the	1	correct?
1 2		1 2	correct?  A I agree with you, yes.
	MS. PARFITT: And we'll put it up on the		correct?
2	MS. PARFITT: And we'll put it up on the ELMO here.	2	correct?  A I agree with you, yes.
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	Page 214		Page 216
1	I've seen.	1	up here, and I'm going to doc and I'm going to
2	Q Okay. Fair.	2	go ahead and make a notation as you talk, and
3	Now, this is from the Sidney Kimmel	3	we're going to put your initials by that which you
4	Comprehensive Cancer Center, correct?	4	agree or don't agree, or that which resonates with
5	A That's right.	5	you or that which does not.
6	Q And it's entitled "Risk Factors Risk	6	So give me a moment. Hang with me,
7	Factors" excuse me and Symptoms." Do you	7	okay?
8	see that?	8	A Yeah.
9	A I do.	9	Q All right.
10	Q All right. And if you and this is for	10	MS. BROWN: Objection to the exercise.
11	ovarian cancer, you see that?	11	THE WITNESS: And I will say I mean I
12	On the second line, "ovarian cancer," it	12	wasn't you know, that I don't necessarily
13	talks	13	I'm not going to be able to necessarily agree or
14	A Yes.	14	literally disagree with each one of these, but
15	Q Okay. Now, what I'd like you to do is	15	I'll just try to comment on what they what they
16	turn to the second page, and there is a risk	16	have here and what it says to me.
17	factor listed, amongst others. Do you see that?	17	BY MS. PARFITT:
18	A I do.	18	Q All right. Well, why don't we take the
19	Q And it says "Talcum Powder and	19	first one.
20	Asbestos." Do you see that?	20	"Habitual use of talcum powder on the
21	A Yes.	21	genital area may increase the risk for ovarian
22	Q All right. Would you read that, please.	22	cancer, but the evidence is not strong."
23	A "Habitual use of talcum powder on the	23	A Yeah.
24	genital area may increase the risk for ovarian	24	Q Do you agree with that?
25	cancer, but the evidence is not strong. A study"	25	A I agree that the evidence is not strong.
	Dama 215		Dama 217
1	Page 215	1	Page 217
1 2	the first sentence or the whole thing?  Q The whole thing.	1 2	And and I think it's a it's a pretty nuanced
3		3	statement. It may increase, which leaves open
4	A Yep. "A study at Harvard Medical School found that using talc this way doubled the risk,	4	that it may not increase. So I think it's a it's a balanced statement. And their inclusion of
5	but other studies found no increased risk. Some	5	the evidence not being strong is what resonates
6	researchers believe that tale may be carcinogenic	6	with me.
7	because it contains particles of asbestos, a known	7	Q Okay. Do you disagree, though, that
8	carcinogen. It's been shown that rates of ovarian	8	it do you agree or disagree with this
9	cancer are higher than normal in women whose jobs	9	statement: "Habitual use of talcum powder on the
10	expose them to asbestos."	10	genital area may increase the risk for ovarian
	Q All right. Thank you.		
11 12	Fair to say, Dr. Diette, that your	11	cancer, but the evidence is not strong"?  MR. LOCKE: Objection.
13	opinions are contrary to the opinions of what	13	BY MS. PARFITT:
13 14	of those individuals at the Sidney Kimmel	14	
15	Comprehensive Cancer Center?	15	Q Do you agree with that statement?
16	MS. BROWN: Objection to the form of the	16	A I don't literally agree or disagree with
17	question, lacks foundation.	17	it. I mean, I think I break it down the way that I did into those two parts.
18	THE WITNESS: I wouldn't say globally.	18	_
			Q Okay. Well, I have a different
19 20	I mean there's there's things here that	19	question. I know how you want to do it, but I
20	resonate with me just fine.	20	I do get the ask the questions.
21	BY MS. PARFITT:	21 22	MS. BROWN: He answered your question,
22	Q What resonates with you fine and what		Counsel.
23	does not resonate with you?	23 24	BY MS. PARFITT:
24	A Well, so, for example, when Q And if you will, I'm going to put mine	25	Q Habitual question yes or no MS. BROWN: No.
25			

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	Page 218		Page 220
1	BY MS. PARFITT:	1	than "may increase the risk," and it's very
2	Q "Habitual use of talcum powder on the	2	different than saying it causes it.
3	genital area may increase the risk for ovarian	3	BY MS. PARFITT:
4	cancer." True or false?	4	Q Okay.
5	MR. LOCKE: Objection.	5	A So it's it's a pretty vague
6	MS. BROWN: Objection to the form of the	6	statement.
7	question, asked and answered.	7	Q Okay. And I think I hear what you're
8	You can give the same answer again.	8	saying, but my question, and I think you just
9	THE WITNESS: It's	9	answered it, is if if Judge Wolfson says to
10	MS. PARFITT: Counsel, please quit	10	you, Dr. Diette, I would like an answer to my
11	instructing the witness.	11	question: Does the habitual use of talcum powder
12	MS. BROWN: Counsel, don't yell at me.	12	on the genital area increase the risk for ovarian
13	BY MS. PARFITT:	13	cancer?
14	Q Go ahead.	14	My my question to you from Judge
15	MS. BROWN: We can call the Judge.	15	Wolfson.
16	MS. PARFITT: I'm not yelling we can	16	MR. LOCKE: Objection.
17	call the Judge because I'll tell you, I don't	17	MS. BROWN: Objection to the form of the
18	think he'll be she will be impressed.	18	question, asked and answered.
19	MS. BROWN: That's fine. Let's go.	19	THE WITNESS: And whether it does?
20	Let's walk right there and call her right now.	20	BY MS. PARFITT:
21	MS. PARFITT: I'm not going to waste the	21	Q Yeah, the question is
22	time right now.	22	A Well, it doesn't say that, though.
23	MS. BROWN: Okay.	23	Q do you have no, no, I know it
24	THE WITNESS: So I don't see it as a	24	doesn't.
25	true or false questions. I think that there's two	25	A Oh.
	Page 219		Page 221
1	parts, and I I like the way that I answered it.	1	Q I'm representing you've already told
2	BY MS. PARFITT:	2	me what you said about what's here.
3	Q Well, let me ask you this: My if	3	A I see.
4	Judge Wolfson, who is the judge presiding over	4	Q What I'm asking you is, do you have an
5	this case, says to you, Dr. Diette, I've got a	5	opinion whether or not the habitual use of talcum
6	question for you this is in July do you have	6	powder powder on the genital area may increase
7	an opinion whether or not habitual use of talcum	7	the risk for ovarian cancer?
8	powder on the genital area may increase the risk		the fish for ovarian cancer.
	powder on the gental area may increase the risk	8	A Not to quibble, but you just said does
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56 (Pages 218 to 221)

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Gregory B. Diette, M.D.

#### Page 222 Page 224 MS. BROWN: -- of the question, 1 Q Okay. So you agree with "the evidence 1 misstates the document, and it's been asked and 2 is not strong." 2 3 And then what about the next part, "A 3 answered. 4 study at Harvard Medical School found that using 4 THE WITNESS: I'd be careful a lot of 5 5 talc this way doubled the risk, but other studies ways, right? I think it's -- it's easy to say 6 6 found no increased risk." Do you agree with that what, you know, Johns Hopkins is saying. I don't 7 7 statement? know how well this represents Johns Hopkins as an 8 8 entity. I -- like I don't know who controls this MS. BROWN: Objection to the form of the 9 question. 9 website. I don't know who the author was. I 10 10 THE WITNESS: It's -- I would say maybe. don't know if it was -- you know, somebody who was 11 11 And the reason is because they -- they haven't hired for the summer to create a website or 12 12 cited what the Harvard study is. It -- I could whether it's somebody who is a credible 13 13 assume, but I might be wrong that maybe it's the researcher. 14 But I also know that these kinds of 14 Cramer study from '82. Maybe it's not. So I don't know. So if they're citing that, then --15 15 things populate all kinds of different websites, 16 then that might well be a correct statement. And 16 and they're not necessarily like a policy 17 17 it's certainly correct that other studies have statement, you know, of a university or a hospital 18 18 found no increased risk. or an entity. 19 BY MS. PARFITT: 19 BY MS. PARFITT: 20 20 Q And I'll --Q All right. So from your review of the 21 medical and scientific literature, you have seen 21 A I would just be careful, I mean just in 22 where scientists who look at the same scientific 22 terms of saying Johns Hopkins is saying this. 23 and medical literature can arrive at different 23 Q Well, I will represent to you, and you 24 24 can see for yourself, that the Sidney Kimmel opinions, correct? 25 25 MS. BROWN: Objection to the form of the Comprehensive Center puts out this information. Page 223 Page 225 1 Your institution. 1 question. 2 2 THE WITNESS: Are we talking about a MS. BROWN: Objection to the form of the 3 specific topic or just you -- in general, that 3 question, and misstates the document. 4 scientists can disagree with each other? 4 THE WITNESS: It's the same issue. 5 5 BY MS. PARFITT: Right. I mean I know the Sidney Kimmel Cancer 6 6 Q Scientists can disagree with each other. Center, and I work there. It's -- but I don't 7 7 MS. BROWN: Objection to the form. know what the source is of this information, I 8 8 don't know who's the author, and I don't know what THE WITNESS: I think in general, they 9 can disagree about all sorts of things. I don't 9 they expect it to represent in terms of a Johns 10 think there's a good reason to disagree about this 10 Hopkins, you know, point of view. 11 BY MS. PARFITT: 11 topic that we're talking about. 12 12 BY MS. PARFITT: Q Did anyone over at the Sidney Kimmel 13 Comprehensive Cancer Center ever consult you with 13 Q Well, in this particular sentence, Johns 14 Hopkins University is representing to consumers, 14 regard to what language should be included on the 15 15 or anyone who wants to get onto the website, that website with regard to risk factor information? 16 medical schools found -- that a study of the 16 A No. Harvard Medical School found that using talc this 17 MS. BROWN: Objection to the form. 17 18 way doubled the risk, but other studies found no 18 BY MS. PARFITT: 19 19 increased risk. Q Okay. The second part, let's go on. If A Yes. 20 you will, it starts with -- if you can read on 2.0 21 "Some," if you would read that, please. 21 Q Is it fair to say they're communicating 22 that there are science -- there's science out 22 A "Some researchers believe that talc may 23 there that goes both ways? 23 be carcinogenic because it contains particles of 24 MS. BROWN: Objection to the form --24 asbestos, a known carcinogen." 25 25 MR. LOCKE: Objection. Q All right. And do you agree with that

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1	statement?	1	out to the Food and Drug Administration to share
2	MS. BROWN: Objection to the form.	2	your opinions with them?
3	THE WITNESS: Well, I certainly agree	3	A No.
4	that some researchers believe that, because we've	4	Q All right. Other than counsel who has
5	seen it in plaintiffs' experts. So it's on its	5	retained you to provide an expert a legal
6	face, I think it's a a true true statement	6	expert report, have you reached out to any
7	that there are people who believe that.	7	scientific body to share your opinions?
8	And I think the part that asbestos is a	8	MS. BROWN: Objection to the form.
9	known carcinogen is also something I agree with.	9	THE WITNESS: No.
10	BY MS. PARFITT:	10	BY MS. PARFITT:
11	Q Okay. And then it goes on to say:	11	Q Okay. Have you reached out to any
12	"It's been shown that rates of ovarian cancer are	12	medical body to share your opinions?
13	higher than normal in women whose jobs expose them	13	MS. BROWN: Objection to the form.
14	to asbestos."	14	THE WITNESS: No.
15	Do you agree with that statement?	15	BY MS. PARFITT:
16	A So, you know, this language is is not	16	Q Okay. Did you reach out to the Sidney
17	great, right? It has been shown that, right. So	17	Kimmel Comprehensive Cancer Center and the folks
18	we could look at, you know, any one of those	18	over there and share with them what your opinions
19	studies that was done around World War II, for	19	are?
20	example, and if you looked at one that was	20	A No.
21	positive, you could say it was shown that they	21	MS. BROWN: Asked and answered.
22	were higher. I'm not sure whether the general	22	BY MS. PARFITT:
23	proposition has been established, though.	23	Q Do you know Dr. Merlo?
24	Q Okay.	24	A I do.
25	A If you guys are going to whisper, you're	25	Q He's a friend of yours, right?
		1	D 220
	Page 227		Page 229
1	going to miss what I'm saying.	1	A He is.
2	going to miss what I'm saying.  Q No, I was I was just turned.	2	A He is. Q Okay. And you're Facebook friends.
	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.	2 3	<ul><li>A He is.</li><li>Q Okay. And you're Facebook friends.</li><li>A I'm friends with his wife. He and I</li></ul>
2 3 4	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.	2 3 4	A He is.  Q Okay. And you're Facebook friends.  A I'm friends with his wife. He and I might be also, but we're friends in in reality,
2 3 4 5	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.	2 3 4 5	A He is.  Q Okay. And you're Facebook friends.  A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on
2 3 4	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in	2 3 4	A He is.  Q Okay. And you're Facebook friends.  A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on  Q Not just on Facebook.
2 3 4 5	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.	2 3 4 5	A He is.  Q Okay. And you're Facebook friends.  A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on  Q Not just on Facebook.  A Yeah.
2 3 4 5 6	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.	2 3 4 5 6	A He is.  Q Okay. And you're Facebook friends.  A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on  Q Not just on Facebook.
2 3 4 5 6 7	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.  Q Yeah, thank you. And I thought you had	2 3 4 5 6 7	A He is.  Q Okay. And you're Facebook friends.  A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on  Q Not just on Facebook.  A Yeah.  Q Is his wife a doctor?  A She is not.
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2 3 4 5 6 7 8 9 10	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.  Q Yeah, thank you. And I thought you had finished what you were saying because you finished "okay," so I thought  MS. BROWN: That's your "okay," Counsel.  BY MS. PARFITT:	2 3 4 5 6 7 8 9 10	A He is. Q Okay. And you're Facebook friends. A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on Q Not just on Facebook. A Yeah. Q Is his wife a doctor? A She is not. Q Okay. Do you know Dr. April Zambelli-Weiner?
2 3 4 5 6 7 8 9 10 11 12	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.  Q Yeah, thank you. And I thought you had finished what you were saying because you finished "okay," so I thought  MS. BROWN: That's your "okay," Counsel.	2 3 4 5 6 7 8 9 10 11	A He is. Q Okay. And you're Facebook friends. A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on Q Not just on Facebook. A Yeah. Q Is his wife a doctor? A She is not. Q Okay. Do you know Dr. April Zambelli-Weiner? A I do.
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2 3 4 5 6 7 8 9 10 11 12 13 14	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.  Q Yeah, thank you. And I thought you had finished what you were saying because you finished "okay," so I thought  MS. BROWN: That's your "okay," Counsel.  BY MS. PARFITT:  Q I'm sorry. I believe you finished. I'm	2 3 4 5 6 7 8 9 10 11 12 13 14	A He is. Q Okay. And you're Facebook friends. A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on Q Not just on Facebook. A Yeah. Q Is his wife a doctor? A She is not. Q Okay. Do you know Dr. April Zambelli-Weiner? A I do. Q Okay. You have worked with her in the past, correct? A Really briefly, way back when. Q Okay. Do you consider her do you
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.  Q Yeah, thank you. And I thought you had finished what you were saying because you finished "okay," so I thought  MS. BROWN: That's your "okay," Counsel.  BY MS. PARFITT:  Q I'm sorry. I believe you finished. I'm not sure whether the general proposition has been established. So I thought that was the end  A That was the end  Q of your sentence.  A Yeah.  Q Right. Okay. All right.  A Are we done with this one?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A He is. Q Okay. And you're Facebook friends. A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on Q Not just on Facebook. A Yeah. Q Is his wife a doctor? A She is not. Q Okay. Do you know Dr. April Zambelli-Weiner? A I do. Q Okay. You have worked with her in the past, correct? A Really briefly, way back when. Q Okay. Do you consider her do you know she's an epidemiologist, correct? A I think I know that. Q Okay. Do you consider her an epidemiologist with expertise and well received in the medical comm and scientific community?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	going to miss what I'm saying.  Q No, I was I was just turned.  A Okay.  Q I heard what you said. Thank you.  A All right.  Q And fortunately, I have it right here in front of you too.  A Okay, good. Good, good, good.  Q Yeah, thank you. And I thought you had finished what you were saying because you finished "okay," so I thought  MS. BROWN: That's your "okay," Counsel.  BY MS. PARFITT:  Q I'm sorry. I believe you finished. I'm not sure whether the general proposition has been established. So I thought that was the end  A That was the end  Q of your sentence.  A Yeah.  Q Right. Okay. All right.  A Are we done with this one?  Q For the time being, yeah. We may come	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A He is. Q Okay. And you're Facebook friends. A I'm friends with his wife. He and I might be also, but we're friends in in reality, not just on Q Not just on Facebook. A Yeah. Q Is his wife a doctor? A She is not. Q Okay. Do you know Dr. April Zambelli-Weiner? A I do. Q Okay. You have worked with her in the past, correct? A Really briefly, way back when. Q Okay. Do you consider her do you know she's an epidemiologist, correct? A I think I know that. Q Okay. Do you consider her an epidemiologist with expertise and well received in the medical comm and scientific community? MS. BROWN: Objection. Lacks

58 (Pages 226 to 229)

ı	Page 230		Page 232
1	that I saw her was when she was still training at	1	appear and give testimony, correct?
2	Hopkins. And so there's a couple of decades that	2	A Correct.
3	have gone by. So I so I honestly have no idea	3	MS. BROWN: Form.
4	what her reputation is at this point.	4	BY MS. PARFITT:
5	BY MS. PARFITT:	5	Q Right. So no one inquired as to what
6	Q Okay. Did you work with her?	6	your opinions were on this topic; is that correct?
7	A Sort of. Like not we were we were	7	MS. BROWN: Asked and answered.
8	both involved in a research project, but we	8	THE WITNESS: That is correct.
9	weren't both involved in the same part of the	9	BY MS. PARFITT:
10	project. So I it's to say that we worked	10	Q Okay. I'll represent to you that at the
11	together, it's it's a little bit vague in a way	11	hearing, both consumer and industry were invited
12	about whether we did. We traveled together for	12	to attend.
13	one particular research program we were a part of.	13	Are you aware that Dr. McTiernan, who is
14	But	14	an expert in this case, was one of those
15	Q Okay.	15	individuals that was invited to attend?
16	A Like I don't think we published	16	MR. LOCKE: Objection.
17	together. I don't think.	17	MS. BROWN: Objection. Lacks
18	Q Do you think of her as a good scientist?	18	foundation.
19	MS. BROWN: Objection to the form of the	19	THE WITNESS: I don't know.
20	question, calls for speculation.	20	BY MS. PARFITT:
21	THE WITNESS: I I honestly don't know	21	Q Okay. You've read her expert report,
22	what she's what she's up to. I mean it's	22	correct?
23	literally been a couple of decades.	23	A I did.
24	BY MS. PARFITT:	24	Q And you understand that she was one of
25	Q Sure. Well, when you did know her back	25	the coinvestigators with the WHI study?
	Page 231		Page 233
1	a couple of decades ago, did you consider her a	1	MS. BROWN: Objection to the form.
2	good scientist?	2	BY MS. PARFITT:
3	MS. BROWN: Objection to the form,	3	Q One of the cohorts that you rely on.
4	vague, calls for speculation.	4	MS. BROWN: Foundation, speculation.
5	THE WITNESS: I wouldn't say that I know		
6		5	THE WITNESS: That's what I understand.
0	that she wasn't, but I really wasn't very familiar	5 6	BY MS. PARFITT:
7	that she wasn't, but I really wasn't very familiar with what her work was.		
		6	BY MS. PARFITT:
7	with what her work was.  BY MS. PARFITT:  Q Her work. Okay. That's fair enough.	6 7	BY MS. PARFITT:  Q Okay. When you were writing your expert report and researching the cohort studies, did you ever reach out to Dr. McTiernan to consult with
7 8	with what her work was.  BY MS. PARFITT:  Q Her work. Okay. That's fair enough.  Okay. Alrighty. Let's set this aside.	6 7 8	BY MS. PARFITT:  Q Okay. When you were writing your expert report and researching the cohort studies, did you
7 8 9 10 11	with what her work was.  BY MS. PARFITT:  Q Her work. Okay. That's fair enough. Okay. Alrighty. Let's set this aside. Dr. Diette, are you aware that just last	6 7 8 9 10 11	BY MS. PARFITT:  Q Okay. When you were writing your expert report and researching the cohort studies, did you ever reach out to Dr. McTiernan to consult with
7 8 9 10	with what her work was.  BY MS. PARFITT:  Q Her work. Okay. That's fair enough.  Okay. Alrighty. Let's set this aside.	6 7 8 9 10	BY MS. PARFITT:  Q Okay. When you were writing your expert report and researching the cohort studies, did you ever reach out to Dr. McTiernan to consult with her with regard to her thoughts and opinions about
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13 products have a statistically significant 13 from all of the published studies consistently	ш
14 increased risk of 22 to 31 percent of developing 14 shows that women who had ever used talcum	owder
15 ovarian cancer. 15 products in the genital area had a statistically	iowaci
16 A So, first of all 16 significant 22 to 31 percent increased risk of	
17 MS. BROWN: Wait, wait. What's the 17 developing epithelial ovarian cancer compared	with
18 question? 18 women who had never used them. Evidence s	
19 BY MS. PARFITT: 19 that these associations hold across diverse race	-
20 Q And I should add developing epithelial 20 and ethnic groups."	
21 ovarian cancer having used talcum powder products. 21 Did I read that correctly?	
22 MS. BROWN: What's the question? You 22 A You did.	
23 just gave an assumption. 23 Q All right. Do you agree with that	
24 BY MS. PARFITT: 24 statement?	
25 Q Do you 25 MS. BROWN: Objection to the form.	
Page 235 Page	237
1 MS. PARFITT: I just was finishing. 1 THE WITNESS: Well, I think this is	
2 BY MS. PARFITT: 2 compatible with what, you know, her report an	1 her
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3 Q But do you agree with her statement 3 testimony has been generally. I think it's	l her
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Page 240 Page 238 1 Terry, but there's other information in there, 1 search terms that you used in order to do your 2 like from Berge, for example, you know, who points 2 literature review? 3 out that there's no risk seen in the cohort 3 A I didn't -- I didn't write them down, 4 studies. So I think if this were balanced, that 4 but it -- you know, this didn't start as like a --5 5 she would -- she would have more information than like a -- like there's been some searches that 6 6 just that particular statement. I've been involved in where, you know, somebody 7 7 Q Okay. And we'll talk a little bit more might commission a review of a particular topic, 8 about the -- the cohorts in just -- just a moment. 8 and you have to figure out what those search terms 9 Okay. What was the methodology you 9 10 10 employed in order to present the opinions and In this case, there's a really good head 11 11 bases for opinions in your report? start because there's meta-analyses done and 12 12 A So generally, I tried to identify all of there's some other -- some other papers. And so the relevant epidemiologic studies -- is that what 13 13 what I tried to use was the words that the authors you're -- you're asking? 14 used, you know, assuming that they would then link 14 up and find the other -- other articles. 15 Q That is? 15 16 16 A Okay. So -- so like "ovarian cancer," "talc," 17 17 O That is. "talcum powder," probably some -- you know, some 18 words like "risk" and "cause" and -- I think for 18 A And so I tried to find them in an 19 iterative way, you know, meaning that there were 19 that part of it that was -- that was kind of the 20 meta-analyses that had many of them listed. I did 20 bulk of it. There may have been other terms that 21 some searches of their own reference lists to look 21 came up in some of the -- some of the articles 22 that I would search for also, but that -- that was 22 for others. I did searches, you know, using 23 web-based, you know, tools to find other -- other 23 the main ones. 24 24 studies, and tried to get what I thought was a Q Did you search for the word "cancer"? 25 pretty comprehensive group of all the 25 A Oh, well, "ovarian cancer." Page 239 Page 241 1 epidemiologic studies. Q Okay. Did you search for the word 1 2 And then I also tried to read other 2 "asbestos"? 3 things, you know, IARC monographs, other -- like 3 A I did, but differently -- so I did sort 4 reports from like American College of Obstetrics 4 of a separate search for that, which was "asbestos 5 and Gynecology, and -- and get a sense of how some 5 and ovarian cancer." Same approach, but -- but 6 6 of the information was being interpreted by different -- I thought we were just talking about 7 7 other -- other bodies. the talcum powder at the moment. 8 And -- and then ultimately looked at 8 But separately, I did a search for 9 criteria that people recognize as useful for 9 "asbestos and -- and ovarian cancer." And -- and 10 assessing causation, which are labeled sometimes 10 just like for this issue of talcum powder, there Bradford Hill considerations, and then other 11 11 was a good head start from -- from IARC, at least 12 things too. 12 having identified several -- several key studies, 13 13 So besides that, then, you know, looking and then looked for more because there were 14 at the quality of the studies in some cases. So, 14 obviously some that they didn't cite or that 15 for example, were there valid measures of -- of 15 weren't available to them at the time that they 16 exposure that were used, was there evidence for 16 did their -- their review. 17 confounding and bias, and so forth. 17 Q Did you search for the word 18 Q All right. 18 "inflammation"? 19 19 A Meaning especially those latters A I did, for -- part of the searches was 20 aren't -- those latter factors aren't part of 20 for inflammation. Bradford Hill. Like he doesn't talk about, you 21 21 O Okay. 22 know, bias and confounding and validity of the 22 A I should say also -- I mean there's more 23 measures and so forth. So there's more to looking 23 to it if you want, just a little bit more. 24 at it than just Bradford Hill. 24 Q No. Let me ask you a question first. Q Okay. So what was -- what were the 25 25 A Okay.

61 (Pages 238 to 241)

	Page 242		Page 244
1	Q There's no question pending.	1	A Some
2	I assume you did a literature search	2	MS. BROWN: Objection to the form.
3	back in the early part of 2017 when you were first	3	THE WITNESS: Some of it.
4	retained, correct?	4	BY MS. PARFITT:
5	A Correct.	5	Q Okay. And how did you select the
6	Q All right. So did you update that	6	case the cases that became part of your list of
7	literature search?	7	cases on page 13 and 14 of your report?
8	A Oh, yeah.	8	A What does "cases" mean?
9	Q Okay. Did you keep do you keep some	9	Q Studies. You have them listed on
10	kind of recordation of material you had before and	10	page 13, and it carries over to page 14.
11	then what material you're looking at now for	11	A It's the way I describe it, I don't
12	purposes of this most recent report?	12	think I got to finish answering the question about
13	A No, I mean it's not sorted by by when	13	the the rest of the methodology. You'd have to
14	I found it.	14	turn over to page 6, and in the section called
15	Q All right. You represented, at least in	15	"Review of Epidemiology Data," there's a
16	your report, that you looked at the databases	16	description of what I just told you verbally just
17	Medline and Google.	17	a moment ago, which is talking about MedLine and
18	Did you use any other databases for your	18	Google Scholar, and reviewed the reference list of
19	research?	19	the individual studies and the meta-analyses to
20	A Well, scholar Google Scholar as	20	assemble a complete list of studies, and then I
21	opposed to just plain Google and then main Google	21	it goes on. That's not the whole paragraph
22	itself. I don't remember if I used any others.	22	obviously, but that's the that's the general
23	Q Okay. Where in your report do you share	23	method of how I found them.
24	your systematic review and collection of the	24	Q Okay. And what process did you go
25	various literature that formed the bases of your	25	through to select or deselect certain pieces of
	Page 243		Page 245
1	Page 243 opinion?	1	Page 245 literature that you reviewed?
1 2		1 2	
	opinion?		literature that you reviewed?
2	opinion?  A I didn't write that part, I don't think,	2	literature that you reviewed?  A Well, I I included all of the ones
2	opinion?  A I didn't write that part, I don't think, but it I do talk about the the methodology	2 3	literature that you reviewed?  A Well, I I included all of the ones that I could find. I mean we're talking about the
2 3 4	opinion?  A I didn't write that part, I don't think, but it I do talk about the the methodology in general.	2 3 4	literature that you reviewed?  A Well, I I included all of the ones that I could find. I mean we're talking about the epidemiologic studies.
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2 3 4 5 6 7	opinion?  A I didn't write that part, I don't think, but it I do talk about the the methodology in general.  Q Okay. Well, you talk about the methodology on page I believe it's page 4, and there's about two paragraphs there, and then on	2 3 4 5 6 7	literature that you reviewed?  A Well, I I included all of the ones that I could find. I mean we're talking about the epidemiologic studies.  Q We are. We are indeed, yeah.  A So like in terms of the cohort studies, there's only three I could find. There's more
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	opinion?  A I didn't write that part, I don't think, but it I do talk about the the methodology in general.  Q Okay. Well, you talk about the methodology on page I believe it's page 4, and there's about two paragraphs there, and then on the top of page 5, where there's just two full paragraphs.  So my question is, where do you is there anywhere else in your report that you set forth your methodology  A Yeah.  Q employed in order to A Sure, other places Q form the basis for your opinions? A Sorry, I didn't mean to interrupt. Q No, and what I'm saying A Were you done? Q you have a methodology section let's start over.  You have a methodology section of your	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	literature that you reviewed?  A Well, I I included all of the ones that I could find. I mean we're talking about the epidemiologic studies.  Q We are. We are indeed, yeah.  A So like in terms of the cohort studies, there's only three I could find. There's more than three publications that pertain to the three, but I included all three, and I included all the publications I could find on the topic.  But the case-control study, a similar approach, although there's a little bit of confusion with the case controls because there's overlap. There is a redundant publication where some authors are presenting the same data twice, and it's not entirely clear how to unravel them. So I just tried to include as many of those as I could that looked like distinct studies, and I tried to make sure I had the you know, the vast majority of what was being considered in the meta-analysis as well.  Q I think where I'm going is, where do

62 (Pages 242 to 245)

	Page 246		Page 248
1	THE WITNESS: I tried to get them all.	1	of the risk risk estimates, not of the number
2	I wasn't trying to exclude any studies.	2	of cases.
3	BY MS. PARFITT:	3	BY MS. PARFITT:
4	Q So every so may I assume from that	4	Q Correct. So where on this page 13 or 14
5	statement that all of the literature that you've	5	do you tell the reader how many ovarian cancer
6	listed on page 13 and 14 in the cohort studies and	6	cases were part of that study?
7	the meta-analysis is the entire body of literature	7	MS. BROWN: Objection to the form.
8	that you reviewed?	8	THE WITNESS: It's not on there.
9	A Of course not.	9	BY MS. PARFITT:
10	MS. BROWN: Objection to the form.	10	Q Okay. Where on your list of cases, 13
11	THE WITNESS: No, no, what well, I	11	and 14, do you tell the reader the number of
12	guess, if you could, please be very precise what	12	controls that were involved in that study?
13	you're asking.	13	A I didn't I didn't list every single
14	To me what I think we're talking about	14	thing like that on here.
15	is the case-control studies and the cohort	15	Q You didn't list it in your report
16	studies, and so I tried to identify every single	16	either, correct?
17	one of them. So I didn't have an exclusion	17	MS. BROWN: Objection to the form.
18	criteria to say I was going to ignore this one	18	THE WITNESS: Well, this is the report.
19	because it wasn't supportive of my view or	19	BY MS. PARFITT:
20	something like that. I included them all.	20	Q Well, you didn't list it anywhere else
21	I searched for clinical trials, but	21	other that information is not contained in your
22	there weren't any. So that was that was an	22	report. Is that fair?
23	issue as well.	23	MS. BROWN: Objection to the form.
24	BY MS. PARFITT:	24	MR. LOCKE: Objection.
25	Q Were there any studies that you chose	25	THE WITNESS: The sample size?
	Q ore more any states and you enough		THE WITH BOST THE SUMPLE SEET
	Page 247		Page 249
1	not to include on your list of 13 and 14 that you	1	BY MS. PARFITT:
2	had actually reviewed during the course of your	2	Q The sample size is not information that
3	study?	3	you contained that you included in your report,
4	A And we're talking about case-control	4	correct?
5	studies and cohorts.	5	A I did not.
6	Q Correct.	6	MS. BROWN: Same objection.
7	A I didn't wait a minute. I didn't	7	BY MS. PARFITT:
8	deliberately not include any of them. I tried to	8	Q Okay. Where in your report do you tell
9	include every single one, with that exception	9	the reader the country from where these studies
10	being and I don't remember which ones were	10	came from?
11	which, but there were a couple that were	11	MS. BROWN: Objection to the form.
12	redundant. You know, the the authors of these	12	THE WITNESS: I don't list that.
13	haven't in every case been careful about reporting	13	BY MS. PARFITT:
14	findings that are unique.	14	Q Okay. Where do you tell the reader what
15	Q Okay. Focusing now, if I may, on your	15	the mean age of the participants in this study
16	chart, page 13 and 14 of the case-control studies.	16	were?
17	Do you have that in front of you?	17	MS. BROWN: Same objection.
18	A Almost.	18	THE WITNESS: And same answer, I
19	Q Okay.	19	don't I don't list that either.
20	A I do.	20	BY MS. PARFITT:
21	Q All right. Where in this document,	21	Q Where in your report do you tell the
22	page 13 and 14, do you identify the number of	22	reader the number of adjusted variables per study
23	ovarian cases that formed the bases of the study?	23	that were considered?
24	MS. BROWN: Objection to the form.	24	MS. BROWN: Objection to the form.
		44	1415. DICO 1414. Objection to the form.
2.5	THE WITNESS: This is the list of the	2.5	THE WITNESS: I didn't I didn't
25	THE WITNESS: This is the list of the	25	THE WITNESS: I didn't I didn't

63 (Pages 246 to 249)

	Page 250		Page 252
1	capture that here.	1	Q What specific, if any, in vitro studies
2	BY MS. PARFITT:	2	did you consider for purposes of your opinion?
3	Q Okay. And where in your report do you	3	A So I are you good?
4	tell the reader the type of ovarian cancer that	4	Q Yeah, thank you.
5	the women suffered?	5	A Okay. So I I don't know if you're
6	MS. BROWN: Objection to the form.	6	including some animal studies as in vitro studies
7	THE WITNESS: That's not listed on on	7	or whether you just mean sort of like ones that
8	this table either.	8	are that are cell-based or in a dish.
9	BY MS. PARFITT:	9	Q Well, there's a difference, isn't there?
10	Q Did you create this table yourself or	10	A There should be, yeah, but I just
11	did you have assistance?	11	since you're asking the question, I don't know
12	A So, actually, I made this initially, and	12	you, and so I I just want to be clear.
13	there might have been a couple that filtered in	13	Q No, I'm I'm cognizant of the
14	after I started to create it where you know,	14	difference between in vivo and in vitro, so what
15	where I had an assistant, you know, plug in a	15	I what I would ask you is what in vitro studies
16	different study.	16	did you consider for purposes of your analysis?
17	Q Where in your report do you tell the	17	A Yeah, I looked at some. I think the
18	reader if you applied a scoring system to the data	18	ones that were cited by IARC I looked at. I don't
19	and the studies that you reviewed?	19	remember the full list of ones which ones I may
20	A That wasn't	20	have listed, if any, that that I looked at.
21	MS. BROWN: Objection. Lacks	21	But that wasn't really my main my main purpose
22	foundation.	22	in looking at the epidemiology, which was to
23	THE WITNESS: That wasn't my approach.	23	was to look at in vitro studies.
24	BY MS. PARFITT:	24	Q Okay. Was part of your analysis or
25	Q Okay. We'll talk about that in a	25	did part of your analysis include looking at
1	Page 251 minute. Appreciate that.	1	Page 253 in vivo studies?
2	Did you exercise any independent	2	A So I looked at at a bunch of the
3	judgment in determining what cases to include on	3	1:00 4 1 1 4 1 4 1 4 1 1 1 1 1
4		1	different animal studies that were cited, cited in
	this chart of case-control studies on 13 and 14?	4	some of the other documents.
5	this chart of case-control studies on 13 and 14? MS. BROWN: Objection. Asked and		
5 6		4	some of the other documents.
	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive.	4 5	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you
6	MS. BROWN: Objection. Asked and answered.	4 5 6	some of the other documents.  Q Which ones?  A So I don't remember the author names. I
6 7	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT: Q Being inclusive did being inclusive	4 5 6 7	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you
6 7 8	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT:  Q Being inclusive did being inclusive require you to exercise professional judgment with	4 5 6 7 8	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you know, rats, rabbits, primates. I can't remember if there were mouse there were mouse studies as well.
6 7 8 9 10 11	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT:  Q Being inclusive did being inclusive require you to exercise professional judgment with regard to selection of the cases that you reviewed	4 5 6 7 8 9 10	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you know, rats, rabbits, primates. I can't remember if there were mouse there were mouse studies as well.  So whatever that list is that was in
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6 7 8 9 10 11 12	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT:  Q Being inclusive did being inclusive require you to exercise professional judgment with regard to selection of the cases that you reviewed and included for purposes of your analysis?  A So, mostly, yes. What I would say is I	4 5 6 7 8 9 10 11 12 13	some of the other documents.  Q Which ones? A So I don't remember the author names. I mean, there were there were studies of, you know, rats, rabbits, primates. I can't remember if there were mouse there were mouse studies as well.  So whatever that list is that was in IARC that they had considered at that point, and then I think I found a couple more.
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT:  Q Being inclusive did being inclusive require you to exercise professional judgment with regard to selection of the cases that you reviewed and included for purposes of your analysis?  A So, mostly, yes. What I would say is I was trying to understand what the universe was of case controls that were being listed in the meta-analyses, what the case controls were that were informing the opinions of the plaintiffs' experts. And so I didn't want to have some arbitrary rule for saying one shouldn't be in here. I wanted to look at them all. And so my	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you know, rats, rabbits, primates. I can't remember if there were mouse there were mouse studies as well.  So whatever that list is that was in IARC that they had considered at that point, and then I think I found a couple more.  Q What, if any, information did you glean from your review of the in vitro and in vivo studies that formed the basis of your study report?  A Well, mostly so to to think about how for me as an epidemiologist, and not as a cancer biologist or molecular biologist, I wanted
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT:  Q Being inclusive did being inclusive require you to exercise professional judgment with regard to selection of the cases that you reviewed and included for purposes of your analysis?  A So, mostly, yes. What I would say is I was trying to understand what the universe was of case controls that were being listed in the meta-analyses, what the case controls were that were informing the opinions of the plaintiffs' experts. And so I didn't want to have some arbitrary rule for saying one shouldn't be in here. I wanted to look at them all. And so my goal was actually to include them all, and not deselect some because I thought that there was a quality issue with them.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you know, rats, rabbits, primates. I can't remember if there were mouse there were mouse studies as well.  So whatever that list is that was in IARC that they had considered at that point, and then I think I found a couple more.  Q What, if any, information did you glean from your review of the in vitro and in vivo studies that formed the basis of your study report?  A Well, mostly so to to think about how for me as an epidemiologist, and not as a cancer biologist or molecular biologist, I wanted to just understand generally how some of the other entities were wielding that information, right. So that like I wasn't about to become a cancer
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. BROWN: Objection. Asked and answered.  THE WITNESS: I tried to be inclusive. BY MS. PARFITT:  Q Being inclusive did being inclusive require you to exercise professional judgment with regard to selection of the cases that you reviewed and included for purposes of your analysis?  A So, mostly, yes. What I would say is I was trying to understand what the universe was of case controls that were being listed in the meta-analyses, what the case controls were that were informing the opinions of the plaintiffs' experts. And so I didn't want to have some arbitrary rule for saying one shouldn't be in here. I wanted to look at them all. And so my goal was actually to include them all, and not deselect some because I thought that there was a	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	some of the other documents.  Q Which ones?  A So I don't remember the author names. I mean, there were there were studies of, you know, rats, rabbits, primates. I can't remember if there were mouse there were mouse studies as well.  So whatever that list is that was in IARC that they had considered at that point, and then I think I found a couple more.  Q What, if any, information did you glean from your review of the in vitro and in vivo studies that formed the basis of your study report?  A Well, mostly so to to think about how for me as an epidemiologist, and not as a cancer biologist or molecular biologist, I wanted to just understand generally how some of the other entities were wielding that information, right.

	Page 254		Page 256
1	I did want to understand some of their	1	MS. BROWN: What report is
2	underpinnings.	2	MS. PARFITT: Saed.
3	Q Okay.	3	BY MS. PARFITT:
4	A And just so, for example, right, so	4	Q Just give me a moment, Doctor.
5	there's the the studies on migration, for	5	If you turn your attention to page 42.
6	example. I thought it was important to look at	6	A Mm-hmm.
7	those and see what kind of animals, for example,	7	Q At the bottom.
8	had what kind of particles either put into their	8	A Okay.
9	vaginas or put into their uterus, or whatever it	9	Q "I leave a detailed assessment of
10	was, so I could understand what the what the	10	Dr. Saed's efforts to other experts. I did review
11	story was there.	11	Dr. Saed's report and his two depositions and was
12	Q Okay. Do animals have vaginas?	12	struck by the irregularities in his study, which
13	A Some do, yeah.	13	render his results highly questionable."
14	Q You you indicated you're not a cancer	14	So are you or are you not deferring with
15	specialist. Would you defer to on topics	15	regard to opinions concerning what Dr. Saed had to
16	involving those issues to a cancer biologist?	16	say?
17	MS. BROWN: Objection to the form of the	17	MS. BROWN: Objection. Misstates the
18	question.	18	expert report and the opinion.
19	BY MS. PARFITT:	19	THE WITNESS: I I meant to be
20	Q And let me clean it up because I think I	20	somewhat nuanced here, right, which is that you
21	left that off. You are not a cancer biologist,	21	know, it's possible for me to read things and
22	correct?	22	understand that there might be some issues with
23	A Correct.	23	what he's done. I I'm not going to be the
24	Q All right. So would you defer questions	24	person to critique the biologic aspects of his
25	in that wheelhouse to someone who is a cancer	25	work, though.
	Daga 255		Daga 257
	Page 255		Page 257
1	biologist?	1	BY MS. PARFITT:
2	MS. BROWN: Same objection.	2	Q Okay. Fair enough. In fact, let me ask
3	THE WITNESS: So I mostly don't think	3	you, have you read the published scientific
4	about deferring my opinions to other other	4	article by Dr. Saed?
5	people's categorically. You know, so that I think	5	A Not yet.
6	if there were somebody that was a cancer biologist	6	Q Okay. Do you have any plans to do that?
7	and they had an opinion that seemed credible, I	7	A I might. I might, because I was just
8	would take it into account. But to the extent	8	I was curious because I saw some of the like
9	that I needed to understand something, I would	9	the expert reports that came in after I wrote my
10	still rely on my own my own background and	10	report, and there were things that just kind of
11	knowledge.	11	struck me that would be worth trying to sort
1 2			
12	BY MS. PARFITT:	12	through, like whether he had changed like 48 to 36
13	Q All right. You're not a a molecular	13	or yeah, 48 hours to 72 hours, whatever it was,
13 14	Q All right. You're not a a molecular specialist, correct?	13 14	or yeah, 48 hours to 72 hours, whatever it was, that there were like some tables apparently that
13 14 15	Q All right. You're not a a molecular specialist, correct?  MS. BROWN: Objection.	13 14 15	or yeah, 48 hours to 72 hours, whatever it was, that there were like some tables apparently that were the same as an original paper, that the only
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65 (Pages 254 to 257)

	Page 258		Page 260
1	did the report, but I could be wrong.	1	think, but I've certainly read other I mean
2	Q Well, it's available now, isn't it?	2	others that aren't on either of those topics.
3	A That's what I've heard.	3	Q Would you agree would you agree that
4	MS. BROWN: Objection to the form.	4	IARC is a well-respected scientific organization?
5	BY MS. PARFITT:	5	MS. BROWN: Object I'm sorry. I
6	Q But you've not seen it.	6	didn't hear the question.
7	A No. I just I mean like I mean	7	BY MS. PARFITT:
8	it sorry, it's the way I think. It sounds like	8	Q Would you agree that IARC is a well-
9	two different time periods. One was	9	respected scientific organization?
10	Q No.	10	MS. BROWN: Objection to the form.
11	A before the report and one was between	11	THE WITNESS: It's it's hard for me
12	then and now.	12	to characterize whole organizations, you know, in
13	Q No, my question goes	13	terms of whether they're well respected or by whom
14	MS. BROWN: Wait, he's finishing. Let	14	or when, but generally speaking, you know, they
15	him finish.	15	they do produce some some credible documents.
16	BY MS. PARFITT:	16	BY MS. PARFITT:
17	Q My question are you done?	17	Q They do produce some credible documents
18	A I'm good.	18	It's IARC is part of the World Health
19	Q My question really goes to, is it fair	19	Organization, correct?
20	to say that you have not read Dr. Saed's published	20	A It is.
21	peer-reviewed article at the time of your	21	Q Okay. And when IARC has its meetings to
22	deposition?	22	discuss classification of carcinogens, it invites
23	A That is correct.	23	world-renowned experts for whatever area and
24	THE WITNESS: Sorry.	24	specialty is being discussed. Is that fair?
25	MS. BROWN: That's all right.	25	MS. BROWN: Objection to the form.
	Page 259		Page 261
1	Page 259	1	Page 261
1	BY MS. PARFITT:	1	MR. LOCKE: Objection.
2	BY MS. PARFITT:  Q Okay. Now, you've mentioned IARC a	2	MR. LOCKE: Objection. MS. BROWN: Calls for speculation.
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66 (Pages 258 to 261)

Page 262		Page 264
BY MS. PARFITT:	1	Q For instance, if is talcum powder a
Q Do you know what the NTP is?	2	modifiable behavior the use of talcum powder a
A It's like the National Toxicological	3	modifiable behavior?
Program.	4	MS. BROWN: Objection. Misstates his
Q Okay. Has the National Toxicological	5	prior testimony.
	6	THE WITNESS: So it it should be,
talcum powder products?	7	yeah.
A No.	8	BY MS. PARFITT:
Q Has the National Toxicology Program ever	9	Q Okay. Now, Dr. Diette, your paper or
	10	your expert report was signed and executed by you
A No.	11	on February 25th, 2019.
O Have you ever submitted any research to	12	A Correct.
	13	Q Okay. When did you actually finish the
	14	paper, the report?
		A Oh, I think about then. I mean
		O About then?
	1	A I think around then. I mean it's I
		don't know whether it was the day before or the
		or that actual day, but but right around then.
		Q Okay. Are you aware that I guess it
<del>_</del>		was just a couple of months earlier that Health
-		Canada issued and published a critical review and
		assessment of the science, which actually included
		a comprehensive review of the epidemiological
		literature? Did you know that?
THE WITNESS. Wen, I don't you said	25	iterature: Did you know that:
Page 263		Page 265
generally. It could mean a million things to	1	MR. LOCKE: Objection.
different people.	2	MS. BROWN: Objection. That misstates
BY MS. PARFITT:	3	the draft assessment.
Q What's it mean to you?	4	THE WITNESS: I'm familiar with it.
A It depends upon the context. That's why	1	
	5	BY MS. PARFITT:
I'm asking from like an epidemiologic standpoint	5 6	BY MS. PARFITT:  Q Okay. Have you read it?
I'm asking from like an epidemiologic standpoint as opposed to some other context.		
as opposed to some other context.	6	Q Okay. Have you read it?
as opposed to some other context.	6 7	<ul><li>Q Okay. Have you read it?</li><li>A I have.</li></ul>
as opposed to some other context.  Q Well, let's take mesothelioma. What are the risk factors for mesothelioma?	6 7 8	<ul><li>Q Okay. Have you read it?</li><li>A I have.</li><li>Q Have you read it in its entirety?</li></ul>
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as opposed to some other context.  Q Well, let's take mesothelioma. What are the risk factors for mesothelioma?  A Well, if we're talking about, you know,	6 7 8 9 10	Q Okay. Have you read it?  A I have. Q Have you read it in its entirety? A I don't remember if there's like appendices or something, but I read all the you
as opposed to some other context.  Q Well, let's take mesothelioma. What are the risk factors for mesothelioma?  A Well, if we're talking about, you know, asbestos, for example, as one risk factor, then you could use it that way, that that an	6 7 8 9 10 11	Q Okay. Have you read it? A I have. Q Have you read it in its entirety? A I don't remember if there's like appendices or something, but I read all the you know, the mean part of the text. Q Okay. There is also meta-analysis that
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	Page 266		Page 268
1	MS. BROWN: Objection.	1	fair?
2	THE WITNESS: It looks to me as if they	2	MS. BROWN: Objection to the form.
3	create well, so I don't know. So they they	3	THE WITNESS: That looks to be part of
4	have their own process. I don't know anything	4	what they've included in here.
5	about Health Canada, so I don't know what they	5	BY MS. PARFITT:
6	typically do. You know, I've never it's unlike	6	Q And you yourself, for purposes of your
7	some other entities where I would kind of	7	report, looked at case-control studies, cohort
8	understand their process because I've read their	8	studies, and meta-analyses, correct?
9	things before.	9	A I did.
10	I don't I don't know anybody	10	Q Okay. Did Health Canada perform a
11	personally that looks to Health Canada for	11	Bradford Hill assessment of the evidence?
12	information, so I've never had a conversation with	12	MS. BROWN: Objection to the form.
13	anybody about, you know, what their methods are,	13	THE WITNESS: They have a section here.
14	how they go about their business.	14	I mean, there's something here that that
15	But it looks as if what they were trying	15	resembles a Bradford Hill analysis.
16	to do was to try to line up whether there was	16	BY MS. PARFITT:
17	information about where talcum powder is found in	17	Q Okay. Let me direct your
18	Canada, so meaning like, you know, how many	18	MS. BROWN: Take as long as you need,
19	different kinds of products. It looked like they	19	Doctor, to finish your answer.
20	were trying to assess some things about dermal	20	THE WITNESS: Well, I just like I
21	absorption or not, whether it's ingested or not,	21	don't know I don't know how much leeway there
22	whether it's inhaled, whether perineal application	22	is in the world for people to say that they did a
23	matters or not.	23	Bradford Hill analysis just by listing out certain
24	It seems that they commissioned yet	24	keywords, right? I mean it's sort of like a word
25	another meta-analysis of some sort by Dr. Taher,	25	salad exercise to me for some of these cases, and
		25	salad exercise to me for some of these cases, and  Page 269
	another meta-analysis of some sort by Dr. Taher,  Page 267	25	
25	another meta-analysis of some sort by Dr. Taher,		Page 269
25	another meta-analysis of some sort by Dr. Taher,  Page 267  and and then created the document that I guess	1	Page 269
25 1 2	another meta-analysis of some sort by Dr. Taher,  Page 267  and and then created the document that I guess that they put out there for for public comment	1 2	Page 269 so BY MS. PARFITT:
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1 2 3 4	another meta-analysis of some sort by Dr. Taher,  Page 267  and and then created the document that I guess that they put out there for for public comment of some sort.  BY MS. PARFITT:	1 2 3 4	so BY MS. PARFITT: Q I'm sorry. A word what? A Word salad.
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Page 270 Page 272 1 Q So let me just ask --1 Did I read that correctly? 2 MS. BROWN: Wait now, he is not done. 2 MS. BROWN: You didn't, and actually you 3 You can follow up when he is done with -said "consistently" and the word is "consistent." 4 MS. PARFITT: Thank you. 4 MS. PARFITT: Fair enough. 5 5 MS. BROWN: Go ahead, Doctor. BY MS. PARFITT: 6 BY MS. PARFITT: 6 Q Did I read that correctly with that 7 7 Q Okay. Crazy. correction? 8 A Okay. Oh, well, they said like in all 8 A Yes. 9 case-control studies reporting positive outcomes, 9 Q Okay. Do you see where the authors 10 the participants recalled the exposure to talc 10 state that, "Further available data are indicative 11 preceded the reported outcome. I mean that is so of a causal effect"? Do you see that? 11 12 far afield from any realistic epidemiologic 12 A I do. 13 principle that to say that that somehow informs a 13 Q Do you agree with Health Canada that Bradford Hill analysis -- I don't know, maybe 14 14 there was a causal effect drawn from the genital 15 "crazy" is the wrong word. Maybe absurd, maybe use of talcum powder products and ovarian cancer? 15 16 ridiculous. But every person in the world that 16 MS. BROWN: Objection to the form, 17 has a particular event or outcome, everything 17 misstates the draft assessment, lacks foundation. 18 about them preceded them. That isn't the same as THE WITNESS: I don't think so, but for 18 19 temporality. Temporality in the epidemiologic 19 the reason that -- being that this is -- this is 20 world is demonstrating that time flowed from the 20 at some level -- maybe it's a summary, I don't 21 time of the exposure. 21 know -- of what they have from above. But their 22 So, that's why I say like -- you know, I 22 input information into what they're concluding read the words here, I see consistency, 23 23 here is not good. Right. 24 specificity, and so forth, but I don't think their 24 I mean look -- look up a couple of 25 application to this is actually a legitimate 25 sentences under "Biologic plausibility," and they Page 271 Page 273 1 say: "The presence of talc in the ovaries has 1 Bradford Hill analysis. 2 been documented," and cite Heller. And they say, 2 Q All right. So it's absurd, it's crazy, 3 and your opinion is that they did not do a proper 3 "The evidence of retrograde transport supports the 4 Bradford Hill analysis. Is that your opinion? 4 biologic plausibility." 5 5 That Heller study doesn't -- doesn't 6 6 support that, right. So they're -- they're MR. LOCKE: Objection. 7 7 stringing things together here that don't MS. BROWN: Objection to the form. 8 8 literally support I think a conclusive statement BY MS. PARFITT: 9 Q Okay. All right. Let me direct -- did 9 here. 10 they -- let me direct your attention to page 21. 10 And also I would just say too, that when And we'll put that up on the ELMO. 11 they say that -- that with the last part of that 11 12 12 All right. Do you see that? Okay? part you read where it says that "The hazard 13 A I'm on page 21. characterization is qualitative in nature," well, 13 14 Q Page 21, and it's the last paragraph, 14 "qualitative" doesn't tell you something about 15 15 and I'll read it. whether it's a strong association. I mean they --16 "The most recent meta-analysis detailed 16 they've resisted using that -- that word here. 17 above, Taher, et al., 2018, and consistent with 17 BY MS. PARFITT: 18 18 the Hill criteria, suggests a small but Q Okay. So my question for you, 19 Dr. Diette, is do you disagree with the draft 19 consistently statistically significant positive 20 Health Canada assessment which found that there 20 association between ovarian cancer and perineal 21 was a causal relationship between the use of 21 exposure to talc. Further available data are 22 indicative of a causal effect. A clear point of 22 genital talcum powder products and ovarian cancer? 23 departure could not be derived from the available 23 MS. BROWN: Objection. That's not what 24 literature. Consequently, hazard characterization 24 the draft assessment --25 MS. PARFITT: Counsel, objection, form. 25 is qualitative in nature."

	Page 274		Page 276
1	MS. BROWN: You're it misstates the	1	talcum powder products used in the genital area
2	document intentionally attempting to mislead the	2	and ovarian cancer? That's the question.
3	witness.	3	MS. BROWN: Objection to the form of the
4	MS. PARFITT: Objection.	4	question, misstates the document
5	THE WITNESS: So I first of all,	5	BY MS. PARFITT:
6	SO	6	Q You may answer.
7	BY MS. PARFITT:	7	A Is there a specific sentence in there
8	Q And, Doctor, let me just say something.	8	that says that?
9	You can explain, but I have a question, and	9	Q It's the question that I've asked you.
10	then you can explain it if you wish.	10	A Oh, so I can't answer it. I can answer
11	And my question is, do you disagree with	11	the
12	the draft Health Canada assessment which found or	12	Q Is there a specific question
13	concluded that there was a causal relationship	13	MS. BROWN: Wait, wait, let him finish.
14	between the use of genital talcum powder product	14	BY MS. PARFITT:
15	and ovarian cancer?	15	Q 20, 21, 28, and Roman numeral iii?
16	MR. LOCKE: Objection.	16	MS. BROWN: What?
17	MS. BROWN: Objection to the form.	17	THE WITNESS: If there's a specific
18	You can answer it truthfully and	18	sentence that says that, and you want me to agree
19	accurately.	19	or disagree, I can agree or disagree with that
20	THE WITNESS: I can't answer it.	20	sentence.
21	BY MS. PARFITT:	21	What I can't agree with is an entire
22	O You can't wait one second.	22	document because I think it's not fair. I'm not
23	A I cannot answer it.	23	talking about just this one. I think, you know,
24	Q You can't answer the question as to	24	lawyers like to do this, right. They like to say,
25	whether or not you agree that they concluded that	25	Do you agree with a such-and-such paper. Well,
23	whether or not you agree that they concluded that	23	bo you agree with a such-and-such paper. Wen,
	Page 275		D 000
	Page 275		Page 277
1	there was a causal relationship between talcum	1	it's nonsense. You don't agree with the paper.
1 2		1 2	
	there was a causal relationship between talcum		it's nonsense. You don't agree with the paper.
2	there was a causal relationship between talcum powder products and ovarian cancer?	2	it's nonsense. You don't agree with the paper. You agree with the finding or you agree with the
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2 3 4	there was a causal relationship between talcum powder products and ovarian cancer?  A So that MS. BROWN: Objection to the form,	2 3 4	it's nonsense. You don't agree with the paper. You agree with the finding or you agree with the conclusion, but not with the entire thing. So here what I'm saying is, there's an
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	Page 278		Page 280
1	above, Taher, and consistent with the Hill	1	A That sentence is there.
2	criteria, suggests a small but consistent	2	Q All right. Okay.
3	statistically significant positive association	3	MS. BROWN: Counsel, if you're moving to
4	between ovarian cancer and perineal exposure to	4	another area, would
5	talc. Further available data are indicative of a	5	MS. PARFITT: I am.
6	causal effect."	6	MS. BROWN: Would this be a good time
7	MS. BROWN: What's the question?	7	for a break?
8	BY MS. PARFITT:	8	MS. PARFITT: Yeah. I'm going to move
9	Q Do you agree with the conclusions of	9	on and change gears.
10	Health Canada?	10	THE VIDEOGRAPHER: The time is 1:52
11	MS. BROWN: Objection to the form. This	11	p.m., and we are off the record.
12	is not the conclusion section.	12	(Recess.)
13	THE WITNESS: So, first of all, the	13	THE VIDEOGRAPHER: The time is
14	the first sentence that you read there talks about	14	2:04 p.m., and we're back on the record.
15	a significant positive association, which isn't	15	BY MS. PARFITT:
16	the same as cause. Right. And then they say,	16	Q Dr. Diette, you mentioned before the
17	"Further available data are indicative of"	17	break the Heller article, and so I don't misquote
18	I I think if you're trying to say	18	you, what was your position with regard to Heller
19	that something causes something, you come out and	19	and what it stood for?
20	you say it. You don't say, "Further data are	20	A I think if we're talking about the
21	indicative of it." So I I don't think this	21	the right one, it's the one where the ovaries were
22	statement says talcum powder causes ovarian	22	removed from, I think, 24 women, and that 12 12
23	cancer.	23	had said that they were talcum powder users and 12
24	BY MS. PARFITT:	24	not, but they found a they found a similar
	B I MB I I M I I I I		not, out the found a the fround a chimian
25	Q Okay. So your quarrel with Health	25	amount of talc in ovaries regardless of whether
25		25	
	Page 279		Page 281
1	Page 279  Canada is the fact that they didn't say it, Talcum	1	Page 281 they were users or not.
1 2	Page 279  Canada is the fact that they didn't say it, Talcum powder products used in the genital area cause	1 2	Page 281 they were users or not.  Q Okay. Is is it your opinion that
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	Page 282		Page 284
1	(Counsel conferring.)	1	A And it's about the middle of the
2	BY MS. PARFITT:	2	paragraph, and it says it is it says right
3	Q Do you have that in front of you?	3	above it, it says: "None of the exposed subjects
4	A I do.	4	in the study was directly occupationally exposed
5	Q All right. Now, this was a different	5	but all were passively exposed to household
6	Heller article than the one you were referring to?	6	contact. It is unclear why so many of the women
7	A Thank you, yes.	7	giving no exposure history did have detectible
8	Q Okay. All right. Now, let me direct	8	asbestos in their ovaries, although it is known
9	your attention to the Abstract section, the last	9	that there is a background level of asbestos in
10	paragraph.	10	the lung tissue of non-exposed individuals."
11	Okay. And it states: "This study	11	So I I don't know. I just don't
12	demonstrates that asbestos can reach the ovary.	12	that this this cements the idea that that we
13	Although the number of subjects is small, asbestos	13	know something about how asbestos, you know, can
14	appears to be present in ovarian tissue more	14	get to the ovaries.
15	frequently and in higher amounts in women with a	15	Q All right. Let me direct your attention
16	documentable exposure history."	16	to the bottom of 438, top of 439.
17	Did I read that correctly?	17	At the bottom of 438, it says "There
18	A Yes.	18	is," and then it goes on to the top of 439:
19	Q All right. Do you agree with that	19	"There is evidence of transport of particulate
20	statement?	20	matter into the female perineum by the
21	MS. BROWN: Objection to the form.	21	transvaginal route."
22	THE WITNESS: Give me one sec, because	22	A I apologize, I I'm not with you, and
23	I it's been a while since I looked at this.	23	I just
24	MS. BROWN: Take your time, Doctor.	24	Q Oh, sure.
25	THE WITNESS: (Peruses document.) Yeah,	25	A I'm just trying to
	Page 283		Page 285
1	again, like so not entirely.	1	Q It's right here, upper corner, 439.
2	BY MS. PARFITT:	2	A Got you.
3	Q What part what part	3	Q Okay?
4	MS. BROWN: Let him finish.	4	A Yep.
5	BY MS. PARFITT:	5	Q All right, again. "There is evidence of
6	Q What part do you agree with?	6	transport of particulate matter into the female
7	A Well, the I think that it's it's	7	
_			perineum by the transvaginal route in both human
8	not well, so the study demonstrates that	8	perineum by the transvaginal route in both human and animal studies." It cites Egli and Newton,
8 9	asbestos can reach the ovary. I guess if it's		and animal studies." It cites Egli and Newton, 1961. It cites Henderson, 1986; Venter and I'm
Ü	•	8	and animal studies." It cites Egli and Newton,
9	asbestos can reach the ovary. I guess if it's	8 9	and animal studies." It cites Egli and Newton, 1961. It cites Henderson, 1986; Venter and I'm
9 10	asbestos can reach the ovary. I guess if it's definitely there, then and it got there somehow	8 9 10	and animal studies." It cites Egli and Newton, 1961. It cites Henderson, 1986; Venter and I'm sure I'll destroy this name Iturralde, 1979;
9 10 11	asbestos can reach the ovary. I guess if it's definitely there, then and it got there somehow and it wasn't through contamination, you know, of	8 9 10 11	and animal studies." It cites Egli and Newton, 1961. It cites Henderson, 1986; Venter and I'm sure I'll destroy this name Iturralde, 1979; Whittemore, 1988. "Suggested that vaginal
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Gregory B. Diette, M.D.

	Page 286		Page 288
1	prior to '70 1976, Cramer, 1982. The	1	If you know.
2	significance of this detection of talc in the	2	THE WITNESS: Can I assume or
3	majority of exposed women and in all women giving	3	MS. BROWN: No, if you don't know, don't
4	no exposure history is unclear and further studies	4	answer. Then you have no basis to answer the
5	are underway to further elucidate this question."	5	question.
6	Did I read that correctly?	6	BY MS. PARFITT:
7	A Yes.	7	Q My question is, do you know what Ken
8	Q Question: Are there chemical	8	Rothman's area of expertise is?
9	similarities between cosmetic talcs and asbestos?	9	MS. BROWN: Objection.
10	MS. BROWN: Objection to the form.	10	THE WITNESS: Well, he's he's made a
11	THE WITNESS: So some of the same	11	career out of out of case-control studies and
12	some of the same features chemically are present	12	articulating, you know, features of the design and
13	in both.	13	so forth.
14	BY MS. PARFITT:	14	BY MS. PARFITT:
15	Q All right. Set that aside for a minute.	15	Q All right. Is he an epidemiologist?
16	We may come back to that.	16	A Well, that's what I was trying to
17	Dr. Diette, for purposes of your	17	remember. Like, I would only be guessing. Like,
18	opinions in this case, you have stated that the	18	I assume for him to be in that role, he would be,
19	cohort studies lack statistical significance, and	19	but there are people that come to epidemiology
20	only a subset of the case-control studies are	20	from other you know, other backgrounds, and so
21	statistically significant. Therefore, there is a	21	I just don't know his credentials.
22	disparity and inconsistency between cohorts and	22	Q Okay. What about Sander Greenland, do
23	case control.	23	you know who he is?
24	Have I summed it up pretty well?	24	A I know the name, but I don't know him.
25	A That that's one of the one of the	25	Q Okay. Have you ever do you know what
	Page 287		Page 289
1	Page 287 bits of evidence of inconsistency.	1	Page 289 kind of scientist Sander Greenland is?
1 2		1 2	
	bits of evidence of inconsistency.		kind of scientist Sander Greenland is?
2	bits of evidence of inconsistency.  Q Okay. Would you agree that to disregard	2	kind of scientist Sander Greenland is?  MS. BROWN: Objection. Form.
2	bits of evidence of inconsistency.  Q Okay. Would you agree that to disregard study results based upon whether they are	2 3	kind of scientist Sander Greenland is?  MS. BROWN: Objection. Form.  THE WITNESS: I do not.
2 3 4	bits of evidence of inconsistency.  Q Okay. Would you agree that to disregard study results based upon whether they are statistically significant or not statistically	2 3 4	kind of scientist Sander Greenland is?  MS. BROWN: Objection. Form.  THE WITNESS: I do not.  MS. BROWN: Foundation.
2 3 4 5	bits of evidence of inconsistency.  Q Okay. Would you agree that to disregard study results based upon whether they are statistically significant or not statistically significant would be a mistake?	2 3 4 5	kind of scientist Sander Greenland is?  MS. BROWN: Objection. Form.  THE WITNESS: I do not.  MS. BROWN: Foundation.  BY MS. PARFITT:
2 3 4 5 6	bits of evidence of inconsistency.  Q Okay. Would you agree that to disregard study results based upon whether they are statistically significant or not statistically significant would be a mistake?  MS. BROWN: Objection to the form.	2 3 4 5 6	kind of scientist Sander Greenland is?  MS. BROWN: Objection. Form.  THE WITNESS: I do not.  MS. BROWN: Foundation.  BY MS. PARFITT:  Q Okay. All right. Do you know Timothy
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73 (Pages 286 to 289)

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	Page 290		Page 292
1	Dr. Diette, that this is Chapter 2 out of the	1	MS. BROWN: I have a continuing
2	Third Edition, Modern Epidemiology.	2	foundation.
3	Do you see that?	3	MS. PARFITT: That's fine, Counsel.
4	A I do.	4	MS. BROWN: objection to this
5	Q Okay. And if you look at the front of	5	exhibit, for which no foundation has been laid.
6	it, it has three authors.	6	BY MS. PARFITT:
7	Do you see that?	7	Q All right. Again, I'm referring to the
8	A I do.	8	category consistency which I represent that is in
9	Q Okay. The first one is Ken Rothman. Do	9	Chapter 2 of the Rothman book, and we can just go
10	you see that?	10	ahead and circle the paragraph that starts: "One
11	A Correct.	11	mistake in implementing the consistency criterion
12	Q The second one is Sander Greenland.	12	is so common that it deserves special mention. It
13	A Correct.	13	is sometimes claimed that a literature or set of
14	Q And the third author is Tim Lash. Do	14	results is inconsistent simply because some
15	you see that?	15	results are statistically significant, and some
16	A I do.	16	are not."
17	Q And they are the book that they have	17	Did I read that correctly?
18	authored is called Modern Epidemiology, Third	18	A You did.
19	Edition. Do you see that?	19	Q "This sort of evaluation is completely
20	A I do.	20	fallacious, even if one accepts the use of
21	Q Okay. Let me let me direct your	21	significant testing methods."
22	attention to page 27.	22	Did I read that correctly?
23	MS. BROWN: Counsel, are you going to	23	A You did.
24	lay a foundation for the use of this document?	24	Q All right. Do you agree with that
25	MS. PARFITT: I can just ask a question.	25	statement?
	Page 291		Page 293
1	I can do that.	1	MR. LOCKE: Objection.
2	I can do that. BY MS. PARFITT:	2	MR. LOCKE: Objection. THE WITNESS: So wait a minute, I just
	I can do that. BY MS. PARFITT: Q Let me ask a question.	2 3	MR. LOCKE: Objection. THE WITNESS: So wait a minute, I just want to so there's a couple of statements
2 3 4	I can do that.  BY MS. PARFITT:  Q Let me ask a question.  "To claim that literature, scientific	2 3 4	MR. LOCKE: Objection.  THE WITNESS: So wait a minute, I just want to so there's a couple of statements there. I think the part that makes it agreeable
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2 3 4 5 6 7	I can do that.  BY MS. PARFITT:  Q Let me ask a question.  "To claim that literature, scientific literature, or a set of results reported in scientific literature is inconsistent simply because some results are statistically	2 3 4 5	MR. LOCKE: Objection.  THE WITNESS: So wait a minute, I just want to so there's a couple of statements there. I think the part that makes it agreeable is to say that that if it's claimed that
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	Page 294		Page 296
1	Q Okay. Who is Daniel Ford?	1	Q Do you know about that?
2	A If it's the one that	2	A I'm aware of that.
3	Q Daniel E. Ford.	3	Q Okay. Now, are you did you read
4	A I don't know his middle name, but	4	Dr. Bowman's deposition?
5	there's a Dan Ford at our at our place.	5	A I did.
6	Q Okay. Is the Dan Ford you know vice	6	Q Okay. Did you see that in Dr. Bowman's
7	dean for clinical investigation, Johns Hopkins	7	deposition?
8	School of Medicine?	8	A I saw I'm just trying to remember. I
9	A Yes.	9	saw the Nature article, I think that is more
10	Q Okay. Is he a friend of yours?	10	recently published than you said 2016?
11	A We're friendly. I mean, we don't hang	11	Q Originally, yes.
12	out, though.	12	A Yeah, but I can't remember if 2016 was
13	Q Now, he is with the Institute for	13	in her deposition, but for sure the more recent
14	Clinical and Translational Research; is that	14	one.
15	correct?	15	Q The one in 2019?
16	A He has been. I'm just trying to think	16	A Exactly right, yeah.
17	if that still exists. Because I know there was a	17	Q All right. All right. Let me show you
18	funding issue, so but he he certainly was in	18	then what's been marked as or will be marked as
19	that role, and he may still be.	19	17. And it is the March 2019
20	Q He may what?	20	(Counsel conferring.)
21	A He may still be. I just I just I	21	BY MS. PARFITT:
22	thought I had heard that the ICTRs were going to	22	Q Okay. Let me show you what we will have
23	be not funded anymore.	23	marked as 17, a study that appeared in The
24	Q Okay.	24	American Statistician in 2019. It's Volume 73,
25	A Maybe it's true, maybe not; but I'm just	25	and it's called "Moving to a World Beyond P <
	Page 295		Page 297
1	saying for sure he was part of that.	1	0.05."
2	Q Mm-hmm. Okay. Sure. Okay.	2	Do you see that?
3	All right. Are you a member and I'm	3	A Actually, I was just sort of flipping
4	assuming you're not because you're not a	4	through to see what I'm looking at. Oh, so the
5	statistician, but I should assume nothing.	5	title, yes.
6	Are you a member of the American	6	
			O Okay. Is this a document you were
7	Statistical Association?		Q Okay. Is this a document you were
7 8	Statistical Association?  A Lam not	7 8	referring to?
8	A I am not.	7 8	referring to? A No.
8 9	<ul><li>A I am not.</li><li>Q Okay. Do you know who they are?</li></ul>	7 8 9	referring to?  A No. Q No?
8 9 10	<ul><li>A I am not.</li><li>Q Okay. Do you know who they are?</li><li>A Not not really. I mean, it it</li></ul>	7 8 9 10	referring to?  A No. Q No? A I was referring to the one in Nature
8 9 10 11	A I am not. Q Okay. Do you know who they are? A Not not really. I mean, it it sounds like the name gives them away, but I	7 8 9 10 11	referring to?  A No. Q No? A I was referring to the one in Nature that I think reports about this.
8 9 10 11 12	A I am not. Q Okay. Do you know who they are? A Not not really. I mean, it it sounds like the name gives them away, but I don't I don't know, you know, who they are as	7 8 9 10 11 12	referring to?  A No. Q No? A I was referring to the one in Nature that I think reports about this. Q Yes. Okay. Let's go ahead and get that
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8 9 10 11 12 13 14 15 16 17 18 19 20 21	A I am not. Q Okay. Do you know who they are? A Not not really. I mean, it it sounds like the name gives them away, but I don't I don't know, you know, who they are as an entity otherwise. Q That's fair. Okay. Are you aware that due to a widespread misuse by scientists and researchers regarding statistical significance and p-values, that the American Statistical Association issued a statement back in 2016 warning the scientific community of this misuse and urging them to cease and desist with the p-value?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	referring to?  A No. Q No? A I was referring to the one in Nature that I think reports about this. Q Yes. Okay. Let's go ahead and get that marked, and we'll talk about all three. (Diette Exhibit No. 17 was marked for identification.) MS. PARFITT: Let's have marked as Exhibit No. 18. (Diette Exhibit No. 18 was marked for identification.) BY MS. PARFITT: Q And I will represent that 18 is a Sander

75 (Pages 294 to 297)

A Yes. Q Okay, Have you had an opportunity to read Exhibit No. 18? A 1 have. Q Okay, Exhibit 17, which is the Wasserstein article, have you had an opportunity to read it prior to today? A 7 his – this – this one, no. Q Okay, All right. Let's first take a moment and discuss what's been marked as 18. Excuse me. No. 18. 18. A 7 his – this one, no. Statistical Society's concern of the misuse of statistical significance and p-value, that they liferally used their March 2019 research paper and devoted attention to this issue and attached almost 40 papers on statistical inference? Are you aware of that? MS. BROWN: He's never seen it, so he needs – specially used their March 2019 research paper and devoted attention to this issue and attached almost 40 papers on statistical inference? Are you aware of that? MS. BROWN: Objection to the form, misstates the facts. Are you referring to  MS. BROWN: Coljection. Jo MS. BROWN: Coljection. Lacks foundation, misstates the facts. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that there was a – a journal issue that had many articles. I MS. BROWN: Objection to the form. THE WITNESS: I saw that the count was, but there - it's probably the same thing we're talking about, but I'm not sure.  BY MS. PARFITT:  O Q Okay, Did you have a chance to read those 40 or so articles?  O Q Okay, Did read that correctly?  A Veal. Q Okay, All right. Let's		Page 298		Page 300
Q Okay. Exhibit No. 18?  A I have. Q Okay. Exhibit 17, which is the Wasserstein article, have you had an opportunity to read it prior to today? A This - this one, no. Q Okay. All right. Let's first take a moment and discuss what's been marked as 18. Excusse me. No, 18. 18. Are you aware that due to the American 18. Statistical Society's concern of the misuse of statistical significance and p-value, that they 15 literally used their March 2019 research paper and devoted attention to this issue and attended almost 40 papers on statistical inference? Are 17 you ware of that?  MR. DCCKE: Objection. MS. BROWN: Objection to the form, 22 misstates the facts. Are you referring to Eshibit 17? MS. PARFITT: No. 17. 17. MS. PARFITT: No. 17. 17. MS. PARFITT: No. 17. 17. MS. BROWN: Yes, 17. MS. PARFITT: No. 17. 17. MS. BROWN: Objection. Lacks foundation, misstates the facts. MS. BROWN: Objection. Lacks foundation, misstates the facts. MS. BROWN: Objection. Lacks foundation, misstates the facts. MS. BROWN: Objection to the form. MS. BROWN: Objection to the form. The WITNESS: I saw that there was a - a journal issue that had many articles. I whose 40 or so articles?  MS. BROWN: Objection to the form. The WITNESS: I saw that there was a - a journal issue that had many articles. I whose 40 or so articles?  MS. BROWN: Objection to the form. The WITNESS: I saw that there was a - a journal issue that had many articles. I whose 40 or so articles?  MS. BROWN: Objection to the form. The WITNESS: I saw that there was a - a journal issue that had many articles. I whose 40 or so articles?  MS. BROWN: Objection to the form. The WITNESS: I saw that there was a - a journal issue that had many articles. I what to do about the very hard problem separating vising afform horse in data and making decisions under uncertainty. Fear not, in this issue, and those 40 or so articles?  MS. BROWN: Objection to the form. The WITNESS: I are that the data to more the provoking papers from forward-looking statisticians, help is on the way."  MS. BROWN: Obje	1	A Yes.	1	MS. BROWN: before you ask him any
a read Exhibit No. 18?  4	2	Q Okay. Have you had an opportunity to	2	
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	Page 302		Page 304
1	"Don't' is Not Enough." Do you see that?	1	statistical significance or lack thereof."
2	A Yes.	2	Do you agree with that statement?
3	Q All right. The first sentence says:	3	MS. BROWN: Objection to the form.
4	"There's not much we can say here about the perils	4	And, Doctor, if you need to read the
5	of p-values and significance testing that hasn't	5	whole article to answer these questions
6	already that hasn't been said already for	6	MS. PARFITT: Counsel, don't coach the
7	decades."	7	witness.
8	Did I read that correctly?	8	MS. BROWN: you should do that.
9	A Yes.	9	Yeah, but you are knowingly
10	Q And then it goes down to the first one:	10	BY MS. PARFITT:
11	"Don't base your conclusions solely on whether an	11	Q Go ahead, Doctor.
12	association or effect was found to be	12	MS. BROWN: putting a document in
13	statistically significant. The p-value passed	13	front of him that he's never seen, so we're not
14	some arbitrary threshold such as $p < 0.05$ ."	14	going to sit here
15	Did I read that correctly?	15	BY MS. PARFITT:
16	A Yes.	16	Q I'm asking you a question, Dr. Diette
17	Q Do you agree with that statement?	17	MS. BROWN: and play cherry-
18	MR. LOCKE: Objection.	18	picking statements to get
19	THE WITNESS: So there's a lot to this,	19	BY MS. PARFITT:
20	right. I mean because, I mean, the lead in to it,	20	Q do you agree that one should not
21	it says it says that there's not much to say	21	conclude anything about scientific or practical
22	here, you know	22	importance based on statistical significance or
23	BY MS. PARFITT:	23	lack thereof? Do you agree with that?
24	Q That hasn't been said.	24	MR. LOCKE: Objection.
25	A hasn't been said for decades.	25	MS. BROWN: Same objection.
	Page 303		D 20F
			Page 305
1	MS. BROWN: Wait, wait, let him finish.	1	THE WITNESS: So, anyway, I think by
2	MS. BROWN: Wait, wait, let him finish. THE WITNESS: And and that's	2	THE WITNESS: So, anyway, I think by saying "don't conclude anything," I think makes
2	MS. BROWN: Wait, wait, let him finish. THE WITNESS: And and that's that's pretty well, I can't say it's true	2 3	THE WITNESS: So, anyway, I think by saying "don't conclude anything," I think makes this not a very agreeable statement for me.
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	Page 306		Page 308
1	did not. These errors waste research efforts and	1	is that correct?
2	misinform policy decisions."	2	A I didn't.
3	Did I read that correctly?	3	MS. BROWN: Asked and answered.
4	A You did.	4	BY MS. PARFITT:
5	Q Do you agree with that?	5	Q All right. Now, let me have marked now
6	MS. BROWN: Objection to the form.	6	as Exhibit No. 19.
7	MR. LOCKE: Objection.	7	(Diette Exhibit No. 19 was marked
8	THE WITNESS: To me it's overly broad,	8	for identification.)
9	and I think that I think that if we go through	9	BY MS. PARFITT:
10	and we find a sentence or two in here that are	10	Q Do you have that, Doctor?
11	agreeable or not, there's a there's a much,	11	Take a look at that, if you will.
12	much bigger proposition here about what's going	12	A (Peruses document.) So is this meant to
13	on, and I don't think it boils down to any one of	13	be a couple of things?
14	these sentences.	14	Q It's two things. I will represent to
15	And I think this looks like a passionate	15	you that the face sheet states "Johns Hopkins
16	opinion piece, right. That's calling it an	16	Institute for Clinical and Translational
17	article, but it's a commentary. And, you know,	17	Research." The American Statistician special
18	these guys might believe that, but I don't I	18	issue, "Moving to a World Beyond P < 0.05." It's
19	don't think it's a mainstream view, and it's not	19	dated March 25, 2019. It has The American
20	my view, you know, without any qualifications	20	Statistician on the side.
21	that that that statement is correct either.	21	A What are we I'm confused, though.
22	Q Okay. Are you aware that over 800	22	This is this is Exhibit 17 with something
23	statisticians and scientists signed on to this	23	attached to it or
24	document to push the concept of abandoning	24	Q You know, that's exactly it. And if you
25	statistical significance?	25	look at Exhibit 19
20	suassical significance.	20	TOOK W. EARION 19
	Page 307		Page 309
1			
_	MS. BROWN: Objection to the form.	1	A Mm-hmm.
2	MS. BROWN: Objection to the form. MR. LOCKE: Objection.	1 2	A Mm-hmm. Q it is moving it states "Moving to
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Page 310 Page 312 1 significance with the researchers at Johns 1 read all 800, but I looked to see if there were 2 Hopkins? 2 people from Hopkins in particular that signed it, 3 And that's a mouthful. So let me make 3 and I knew one of the two. 4 4 Q Okay. Let me show you what we'll have it really clear. 5 MS. BROWN: Let me object --5 marked as Exhibit No. 20. And I will represent to 6 6 MS. PARFITT: I move to strike the you that it is a list of the 800 signatories that 7 7 question. joined together to support this movement to 8 MS. BROWN: You're going to strike it? 8 abandon p-value in statistical significance. 9 MS. PARFITT: Yeah, let me strike it. 9 (Diette Exhibit No. 20 was marked 10 BY MS. PARFITT: 10 for identification.) 11 Q Were you aware, Dr. Diette, that the 11 MS. PARFITT: Again, Counsel, I 12 division of Clinical and Translational Research 12 apologize. Apparently, we only have one copy of 13 over at Hopkins had distributed to its scientists 13 this document. 14 this group of 43 articles, including the 14 MS. BROWN: So is it the blog soliciting 15 Wassertine -- Wasserstein, for purposes of 15 the signatures, or is it just the list? 16 educating them with regard to this concern over 16 MS. PARFITT: It is the list of the misuse of statistical significance? 17 17 signatories. 18 MS. BROWN: I object to a complete 18 MS. BROWN: Okay, that's fine. 19 misrepresentation of the exhibit and to 19 BY MS. PARFITT: 20 foundation. 20 Q Do you see that? 21 THE WITNESS: So I mean, there's a lot 21 A I do. 22 of things, right. I'll try to answer as many as I 22 Q Okay. Do you know an Elizabeth Ogburn? 23 A I don't. I saw her name on here, but 23 24 So one is that I probably got something 24 I -- I don't know her. 25 because I'm -- I've been part of the ICTR, and I 25 Q All right. Do you know Daniel Page 311 Page 313 use the resources, I'm one of the people who 1 Sharfenstein (phonetic)? 1 2 2 helped to write the grant to get it funded, and A Sharfstein, and I know him. Yeah. 3 so -- like I get a zillion things that fly by. 3 Okay. Is that -- do you know anyone 4 I don't know if I saw this or not, but I 4 else that might appear on that list? 5 probably wouldn't have clicked on if it came 5 A I don't know. I didn't read it. I 6 6 through like an e-mail because I had already seen just -- I literally just did a word search for 7 7 it, like, as part of this -- as part of the Bowman "Hopkins," and I came up with like one person 8 8 whose name is Hopkins who works in England, and deposition. 9 9 BY MS. PARFITT: another one, something Hopkins Institute, which is 10 Q Mm-hmm. 10 not, and then two from Johns Hopkins. 11 Q Okay. When did you do this research? 11 A But other than that, I mean, I think 12 it's -- I think they're smart to do it. They 12 A In the last week. I mean, after -should always put stuff out there for people to 13 after reading the Bowman deposition. 13 14 read. It doesn't mean that we're going to get rid 14 Q All right. So you read the Bowman 15 deposition, and then you -- what caused you then 15 of p of 0.05. It doesn't mean we're going to get 16 rid of statistical significance. They're just 16 to -- to go back and look at that or for that? 17 saying it's an interesting read. 17 A Well, because it sounds like an 18 interesting topic, and, you know, who knows, maybe 18 Q Do you know any of the signatories to 19 one day it either will or won't change, but it's 19 this particular document? 20 an interesting thing to read about. And so I 20 A I found one. One that I know 21 wanted to just sort of see what -- what you guys 21 personally, and I'm just trying to remember if 22 there was anybody else that I saw. 22 were driving at. And then since I saw that there 23 Q Well, let me show you what we'll have 23 were 800 signatories, I just figured I would see 24 marked as Exhibit No. 20. 24 if there was anybody at Hopkins that was part of 25 25 A Yeah, so let me just say, so I didn't it or not.

79 (Pages 310 to 313)

	Page 314		Page 316
1	Q Mm-hmm. And you found a couple of	1	significance and p-values?
2	people from Hopkins?	2	A Yeah, well, I'd say the real world,
3	A Yeah, I found two. One I know, one I	3	right. And the real world
4	don't.	4	Q I'm sorry. You're in the real world?
5	Q All right. Again, you were not one of	5	A Real world, yeah.
6	the signatories?	6	Q Okay. And what's the real world doing?
7	A Still true, yeah.	7	A Well, the real world, if I want to write
8	Q Okay. Okay. What position does	8	a grant, I have to provide people with a sample
9	Dr. Sharfstein hold within the University?	9	size estimate of what it is that I'm looking for,
10	MS. BROWN: Objection. Speculation.	10	and the sample size estimate is almost always
11	THE WITNESS: He's been in the	11	based on hypothesis testing. And you have to
12	Department of Biostatistics, and I don't know	12	declare a certain p-value that you find to be a
13	what what other ways to label what he what	13	credible one.
14	his positions are.	14	So I can't just say, I've decided
15	BY MS. PARFITT:	15	because I read some editorial that I'm not going
16	Q Okay. From the time you saw the	16	to use a p-value of 0.05. That I'm still stuck
17	discussion about statistical significance and a	17	with 0.05 as a as an estimate. And so if I
18	movement away from that and did your bit of	18	want to have any success getting a grant, I'm
19	research, did you ever call Dr. Sharfstein to talk	19	going to have to still use the rules that we've
20	to him about it?	20	used for years.
21	A Not yet. I'm hoping I'll just run into	21	And if I publish a paper, I happened to
22	him at some point and and ask him about that.	22	look because I thought it was curious, I went on
23	Q Is the is your interest strong enough	23	New England Journal's website
24	that you might reach out to him?	24	Q Yes.
25	MS. BROWN: Objection to the form.	25	A and they have an extensive list of
	Page 315		Page 317
1	-	1	-
1 2	What what interest are we talking about?	1 2	ways in order to represent your p-values and your
2	What what interest are we talking about? BY MS. PARFITT:		ways in order to represent your p-values and your confidence intervals that you have to adhere to if
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2 3 4	What what interest are we talking about? BY MS. PARFITT: Q Interest in this science that you have indicated yourself seems to be pretty important.	2 3	ways in order to represent your p-values and your confidence intervals that you have to adhere to if
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		1	
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1	Greenland and McShane. Or maybe not. Maybe	1	took wasn't anything novel or different. I mean,
2	that's wait a minute, I could be wrong. No,	2	I don't know at all what his plans are going
3	it's it's those three.	3	forward, but he still works at the University
4	Q And again, you don't know do you know	4	where we still compete for NIH grants
5	any of them? I know you don't know Dr. Greenland.	5	Q Mm-hmm.
6	Do you know any of the others?	6	A and I haven't seen any change in the
7	A I do not.	7	NIH's posture on this, and I haven't seen any, you
8	Q Okay. So if I understand your opinion	8	know, ground swell of support for just doing
9	today, you still believe in the strength of a	9	whatever you feel like in order to publish your
10	statistical significance versus not statistically	10	paper.
11	significant?	11	Q Well, are you suggesting that what
12	A It's	12	Dr. Greenland and others and Dr. Wasserstein have
13	MS. BROWN: Objection to the form.	13	suggested to do whatever you let me get your
14	THE WITNESS: It's still a factor to	14	words shall yeah. Okay.
15	consider when either planning, conducting, or	15	MS. PARFITT: Tell you what, let's take
16	interpreting a study.	16	a quick break. I want to find that part, and
17	BY MS. PARFITT:	17	we'll get back. Let's take a quick break.
18	Q Okay. And do you still live in the	18	THE VIDEOGRAPHER: The time is 2:44 p.m.
19	world that there is a threshold of a p-value of	19	We're going off the record.
20	0.05?	20	(Recess.)
21	A It depends.	21	THE VIDEOGRAPHER: The time is 2:53
22	Q Well, what do you mean "it depends"?	22	p.m., and we're back on the record.
23	A I'm going to explain.	23	BY MS. PARFITT:
24	Q Please.	24	Q Dr. Diette, when we left just before the
25	A So that's why I used the example of p at	25	break, you said: "I haven't seen any ground swell
	Page 319		Page 321
1	0.05, right? I could just say, I have decided	1	of support for doing whatever you feel like in
2	that now I only want to do studies with six people	2	order to publish your paper."
3	in them, and I'll be happy to have a p-value of	3	I'm not talking about the publication of
4	0.5. You'd have to wish me luck getting it	4	papers. What I would like to know from you is, do
5	published anywhere because it's not going to	5	you agree, though, when you were evaluating the
6	happen, right?	6	consistency of evidence, that one should not
7	So if I still want to do research and I	7	disregard studies that are nonstatistically
8	still want to get it published, I'm going to have	8	significant and give greater weight to those that
9	to pick a threshold for a p-value that's agreeable	9	are statistically significant?
10	to the peer reviewers and to the editor. And it	10	MS. BROWN: Objection to the form of the
11	doesn't have to be 0.05. In some circumstances it	11	question.
12	might be 0.01. It might be even lower than that.	12	THE WITNESS: I hear two questions
13	But a but a p threshold is necessary, at least	13	there, and the first part I agree with, and the
14	in our current era, if you want to be able to	14	second part, it depends.
15	conduct and talk about your research.	15	BY MS. PARFITT:
16	Q Do you do you think Dr. Sharfstein is	16	Q Okay. Do you agree that when you are
17	going to now have difficulty having his scientific	17	evaluating and weighing evidence, studies, that
18	works published?	18	you should evaluate studies the same whether they
19	MS. BROWN: Objection. Based on what?	19	are statistically significant or not statistically
20	There's no foundation for that question.	20	significant?
21	BY MS. PARFITT:	21	MS. BROWN: Objection to the form. In
22	Q You can answer the question, Doctor.	22	what context?
23	A Well, exactly that. So so Sharfstein	23	THE WITNESS: I don't know what
24	has been involved in some of our research and some	24	"evaluate the same" means. I mean, I think any
25	critical illness stuff, and the approach that we	25	any study that you think should be evaluated

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1	should be evaluated, you know, as thoroughly as	1	BY MS. PARFITT:
2	you can.	2	Q Okay. Now, let's turn to your chart,
3	BY MS. PARFITT:	3	and specifically the studies that you set forth in
4	Q When you're evaluating the consistency	4	your report on pages 13 and 14.
5	of studies, is it proper epidemiology to consider	5	And if you'd go to your report, 13 and
6	those studies whether or not they are	6	14.
7	statistically significant or nonstatistically	7	A I'm sorry, I've got somebody else's
8	significant?	8	thing here.
9	MS. BROWN: Objection to the form.	9	Q That's okay.
10	THE WITNESS: It is. And I think, you	10	A Okay.
11	know, regardless of what Dr. Rothman has written,	11	Q Okay. You got there? All right.
12	you know, it's part of the information that's	12	What I would like all right. So you
13	available to you, and I think to ignore it would	13	have that in front of you, correct, sir?
14	be, you know, not in your best interest.	14	A I do.
15	BY MS. PARFITT:	15	Q Okay. Now, what I'll have marked as
16	Q Okay. And would you agree that one	16	for demonstrative purposes is a chart that we have
17	should not conclude there is no association or no	17	marked as Diette Exhibit 21.
18	difference just because a one study is	18	(Diette Exhibit No. 21 was marked
19	statistically significant and another study is	19	for identification.)
20	significant?	20	BY MS. PARFITT:
21	MS. BROWN: Objection to the form.	21	Q And let me hand that to you.
22	THE WITNESS: And I agree with you,	22	MS. BROWN: Counsel, can you give a
23	especially because you used "just because."	23	representation for the record about what
24	BY MS. PARFITT:	24	Exhibit 21 is?
25	Q All right. So maybe what do you	25	MS. PARFITT: Yes, I was about to do
	Page 323		Page 325
1	9		
_	mean?	1	that.
2	A No, it's a good sentence. I mean, I	1 2	that.  MS. BROWN: Thank you.
2	A No, it's a good sentence. I mean, I	2	MS. BROWN: Thank you.
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	Page 326		Page 328
1	that Dr. Diette listed in his report on page 13	1	MS. PARFITT: Yeah, there you go.
2	and 14 and has put them on a graph.	2	There you go, Doctor.
3	MS. BROWN: Who who put them on a	3	BY MS. PARFITT:
4	graph and what is the graph?	4	Q Doctor, I've handed you what's marked as
5	MS. PARFITT: Counsel	5	Exhibit 22. It is the an article by Patricia
6	MS. BROWN: Well, I'm going to have an	6	Hartge dated 1983 in JAMA. Do you see that?
7	objection to this document, and I just want to	7	A I do.
8	MS. PARFITT: You can. You can object	8	Q Okay. And at the top of the study, she
9	to this	9	has a table entitled "Estimated Relative Risk."
10	MS. BROWN: make sure I'm properly	10	Do you see that?
11	objecting, because I don't know what it is, who	11	A I do.
12	made it, based on what, and to the extent the	12	Q And I'll put this up on the ELMO.
13	doctor needs the underlying studies to answer your	13	MS. PARFITT: Okay. And it's hard to
14	questions. We'll	14	see. We'll have to zero in there. There you go.
15	MS. PARFITT: Counsel, no speaking	15	Okay.
16	objections.	16	BY MS. PARFITT:
17	MS. BROWN: I just want to object to	17	Q You'll see on your chart you had listed
18	this.	18	for Hartge, 1983, a relative risk of 0.7 with a
19	BY MS. PARFITT:	19	confidence interval of 0.40 to 1.10.
20	Q Dr. Diette	20	Do you see that?
21	MS. PARFITT: I understand, Counsel. I	21	A Uh
22	know what you're doing.	22	Q Look at your
23	MS. BROWN: The name is Diette.	23	A I do, yep.
24	MS. PARFITT: Diette?	24	Q on page 14.
25	MS. BROWN: Diette.	25	Okay. Now, look at the table of the
	113, 213 W.W. 2.000.		
	Page 327		Page 329
1	1.60 D. D. D. D. D. L.		
	MS. PARFITT: Diette.	1	Hartge study under "Genital Talc Use."
2	MS. PARFITT: Diette. BY MS. PARFITT:	1 2	Hartge study under "Genital Talc Use."  Do you see that?
2	BY MS. PARFITT:	2	Do you see that?
2 3	BY MS. PARFITT:  Q I'm sorry, Dr. Diette. I'm not doing it	2 3	Do you see that? A I do.
2 3 4	BY MS. PARFITT:  Q I'm sorry, Dr. Diette. I'm not doing it to annoy you.	2 3 4	Do you see that?  A I do. Q Okay. And do you see where Dr. Hartge
2 3 4 5	BY MS. PARFITT:  Q I'm sorry, Dr. Diette. I'm not doing it to annoy you.  A You've had it you've had it right all	2 3 4 5	Do you see that?  A I do. Q Okay. And do you see where Dr. Hartge reports that the relative risk for genital use
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	Page 330		Page 332
1	saying is not right.	1	MS. BROWN: Okay. Then let him
2	MS. PARFITT: Counsel, that's it. No.	2	MS. PARFITT: I just don't want you
3	I'm sorry.	3	coaching
4	MS. BROWN: Are you intentionally	4	MS. BROWN: answer the question.
5	misrepresenting what's in the paper?	5	MS. PARFITT: and touching the paper
6	MS. PARFITT: Counsel, if you heard my	6	and pointing at things.
7	question I think Dr. Diette understands the	7	MS. BROWN: You are intentionally
8	question.	8	misreading this document.
9	BY MS. PARFITT:	9	BY MS. PARFITT:
10	Q Dr. Diette, we have on the table a	10	Q Doctor all right, Dr. Diette, you're
11	genital use, which is 2.5 with a confidence	11	the one I'm interested in hearing from, to be
12	interval of 0.7 to 10.	12	perfectly candid.
13	Do you see that?	13	My question is, are the is the
14	A Yeah, I'm sorry. Can you give me just	14	relative risk that you have listed for Hartge
15	one second?	15	0.70, or should it be 2.5?
16	Q Okay. Of course I can.	16	A You know, the the study report is
17	A Thank you. (Peruses document.)	17	really tough I think to decide that either one of
18	Yeah, I'm with you.	18	them is ideal. And for a couple of reasons, and
19	Q Okay. And the only correction I I	19	one is just because this this genital with an
20	wish to make is that, instead of the 0.70 that you	20	asterisk, it isn't literally just genital
21	have for Hartge, it should be 2.5	21	application. It includes sanitary napkins.
22	MS. BROWN: Objection.	22	And you can see in a lot of the studies
23	BY MS. PARFITT:	23	that people have sort of broken out sanitary
24	Q for the genital	24	napkin use separate from like perineal
25	MS. PARFITT: Let me finish, Counsel.	25	application.
		_	
	Page 331		Page 333
1	Page 331	1	Page 333
1 2	BY MS. PARFITT:	1 2	And so, you know, that's not an ideal
2	BY MS. PARFITT:  Q for the genital use of talc. Do you	2	And so, you know, that's not an ideal measure for this this chart either. I mean, I
2	BY MS. PARFITT:  Q for the genital use of talc. Do you agree with that?	2 3	And so, you know, that's not an ideal measure for this this chart either. I mean, I get your point, the all over is something else.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MS. PARFITT:  Q for the genital use of talc. Do you agree with that?  MS. BROWN: Objection to the form.  THE WITNESS: So, maybe. I'm just trying to think about how I got  BY MS. PARFITT:  Q Sure.  A got here. Because the you know, the text says that it's there were ten users, so I guess like seven cases and three controls.  Q Mm-hmm.  A It said specifically mentioned use on sanitary napkins, underwear, or the genital area.  But then it says but estimated is  2.5, but the small number of exposed women yielded an unreliable estimate. So I  MS. BROWN: It's  THE WITNESS: Yeah  MS. PARFITT: You don't have to show the doctor.  MS. BROWN: Do you want the truth on the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	And so, you know, that's not an ideal measure for this this chart either. I mean, I get your point, the all over is something else. But there's at least you know, there's more than ten people at least in that particular that particular row. So I I'm not sure if either of these is great, but they Q Well, the analysis you went through, did you go through that analysis for each and every one of the studies that you listed when you made a decision as to which odds ratio to select?  A I did.  Q You did.  A I mean, I tried to pick the one that that fit the best.  Q Okay. And is the one that fits the best for Hartge the 0.70, or is the one that fits the best for Hartge the 2.5?  MS. BROWN: Objection to the form.  THE WITNESS: So I don't know. I mean other than the fact that you've got the word "genital" there, I mean "all over" is kind of

1			
	Page 334		Page 336
1	confusing is how you it's not a great study,	1	you did, where is that contained in your report?
2	right. I mean, I'm not saying the study is not	2	MS. BROWN: And you should feel free to
3	great. I'm saying the report of the study doesn't	3	answer both questions since counsel cut you off.
4	really tell us everything that you could really	4	THE WITNESS: I have no idea about what
5	wish to know.	5	you mean by where it is in the report.
6	BY MS. PARFITT:	6	BY MS. PARFITT:
7	Q So would you like to keep your chart	7	Q Well, I only have RRs here. I have a
8	with the 0.70, or do you think the chart should be	8	table. No analyses of the different case
9	modified to say 2.5?	9	controls. Just a table of their relative risks.
10	MS. BROWN: Objection to the form.	10	So, you've now gone through an analysis
11	THE WITNESS: I mean, I'd be happy to	11	of the Hartge case and said, You know, maybe this
12	put both rows there and just with an asterisk, and	12	is what we should have extracted, maybe we should
13	explain, you know, what each one of those is.	13	have looked at this, but I used my judgment and
14	BY MS. PARFITT:	14	put the 0.7.
15	Q Okay. Would you have you done that	15	And what I'm asking is, is that analyses
16	for all the other studies that you've listed here,	16	that you just did for us on the record the kind of
17	wherein there may be data for sanitary napkins and	17	analysis that you did for all the other studies?
18	data for genital use and data for cornstarch? Did	18	And if it was, where in the 51 pages of your
19	you go through that analysis?	19	report or this chart have you included that
20	MS. BROWN: Objection to the form.	20	information?
21	THE WITNESS: So, for this table I	21	MS. BROWN: Objection. Completely
22	haven't, but I have gone through all the sanitary	22	misstates his testimony, as well as the article,
23	napkin findings that I can. And that's one of the	23	as well as the report, as well as the chart.
24	things you'll find in my handwritten notes from	24	THE WITNESS: Let me just see. So
25	the from the prior case.	25	obviously it's not it's not documented, but I
	Page 335		Page 337
1	In terms of cornstarch, that's a	1	think part of what I'm trying to do is communicate
2	different question.	2	what the what the risks are that were reported
3	BY MS. PARFITT:	3	and what their confidence bounds were.
4	Q And, Doctor, I	4	And so, you know, the papers stand for
5	MS. BROWN: Wait, he needs to finish.	5	themselves. They all exist. They're all cited.
6	He's got to	6	We can look at anything we want.
7	BY MS. PARFITT:	7	I think in terms of the cornstarch
8	Q Doctor, that's really not my question.	8	issue
9	MS. BROWN: No, no, no, no, no, he	9	BY MS. PARFITT:
10	BY MS. PARFITT:	10	Q Doctor, I'm not asking about
11	Q My question is this	11	MS. BROWN: Stop cutting him off.
1.0	MG DROWNI G 1	12	DILLIG DADELEE
12	MS. BROWN: Counsel.	12	BY MS. PARFITT:
12 13	MS. BROWN: Counsel. MS. PARFITT: Counsel.	13	BY MS. PARFITT:  Q the cornstarch. We can talk about
13	MS. PARFITT: Counsel. BY MS. PARFITT: Q My question is	13	Q the cornstarch. We can talk about
13 14	MS. PARFITT: Counsel. BY MS. PARFITT:	13 14	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.
13 14 15	MS. PARFITT: Counsel. BY MS. PARFITT: Q My question is	13 14 15	<ul><li>Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.</li><li>MS. BROWN: You cannot continue to cut</li></ul>
13 14 15 16	MS. PARFITT: Counsel. BY MS. PARFITT: Q My question is MS. BROWN: He has to finish the	13 14 15 16	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.  MS. BROWN: You cannot continue to cut him off, or we'll have to call the Judge.
13 14 15 16 17	MS. PARFITT: Counsel. BY MS. PARFITT: Q My question is MS. BROWN: He has to finish the question.	13 14 15 16 17	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.  MS. BROWN: You cannot continue to cut him off, or we'll have to call the Judge.  MS. PARFITT: I don't have a question
13 14 15 16 17	MS. PARFITT: Counsel. BY MS. PARFITT: Q My question is MS. BROWN: He has to finish the question. BY MS. PARFITT:	13 14 15 16 17 18	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.  MS. BROWN: You cannot continue to cut him off, or we'll have to call the Judge.  MS. PARFITT: I don't have a question about cornstarch.
13 14 15 16 17 18	MS. PARFITT: Counsel.  BY MS. PARFITT:  Q My question is  MS. BROWN: He has to finish the question.  BY MS. PARFITT:  Q You're not answering my question. Mine	13 14 15 16 17 18	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.  MS. BROWN: You cannot continue to cut him off, or we'll have to call the Judge.  MS. PARFITT: I don't have a question about cornstarch.  MS. BROWN: He's answering your
13 14 15 16 17 18 19 20	MS. PARFITT: Counsel.  BY MS. PARFITT:  Q My question is  MS. BROWN: He has to finish the question.  BY MS. PARFITT:  Q You're not answering my question. Mine is a very simple one.	13 14 15 16 17 18 19 20	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.  MS. BROWN: You cannot continue to cut him off, or we'll have to call the Judge.  MS. PARFITT: I don't have a question about cornstarch.  MS. BROWN: He's answering your question.
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13 14 15 16 17 18 19 20 21	MS. PARFITT: Counsel.  BY MS. PARFITT:  Q My question is  MS. BROWN: He has to finish the question.  BY MS. PARFITT:  Q You're not answering my question. Mine is a very simple one.  My question was if you'll be patient with me, my question was: The analysis that	13 14 15 16 17 18 19 20 21	Q the cornstarch. We can talk about that later. I'm not talking about cornstarch.  MS. BROWN: You cannot continue to cut him off, or we'll have to call the Judge.  MS. PARFITT: I don't have a question about cornstarch.  MS. BROWN: He's answering your question.  MS. PARFITT: He is not.  MS. BROWN: You have to let him answer

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	Page 338		Page 340
1	direct.	1	BY MS. PARFITT:
2	MS. BROWN: No, you have to let him	2	Q Correct?
3	answer the question or	3	A I did.
4	MS. PARFITT: Counsel.	4	Q Okay. And my last question is, is that
5	MS. BROWN: We're going off the record.	5	the position you wish to take today?
6	MS. PARFITT: Do you want to go we'll	6	MS. BROWN: Objection to the form.
7	go off the record right now.	7	BY MS. PARFITT:
8	MS. BROWN: Yeah, let's go. Fine. Do	8	Q Or would you modify that and use a
9	we need to call the Judge? You have to let him	9	different relative risk? That's all.
10	answer.	10	A I don't
11	MS. PARFITT: We'll call her. We'll	11	MS. BROWN: Objection.
12	call her.	12	THE WITNESS: I don't think anybody is
13	THE VIDEOGRAPHER: The time is 3:09 p.m.	13	well served by looking at this other number, other
14	We're going off the record.	14	than if you're just trying to make a point and
15	(A discussion was held off the record.)	15	be you know, for a plaintiff or something to
16	THE VIDEOGRAPHER: The time is	16	look at this 2.5.
17	3:10 p.m., and we're back on the record.	17	I think if you take this one that says
18	MS. PARFITT: Thank you.	18	there's a small number of exposed women, ten
19	BY MS. PARFITT:	19	people, you know, that yields an unreliable
20	Q And, Dr. Diette, all I'm trying to to	20	estimate. I mean, somebody should fuss about that
21	ask, and obviously very poorly, is the analysis	21	too. So that's not that's not an ideal
22	that you just discussed that you went through with	22	measure.
23	Hartge, as we sat here today and you did it on the	23	If it helps, we can put them on the
24	record, did you do that for all the other studies?	24	table, and it wouldn't really change things,
25	A I tried to.	25	right. You've got confidence bounds from 0.7 to
23	A Tulculo.	23	right. Touve got confidence bounds from 0.7 to
	Page 339		Page 341
1	Q Okay. And so you had to make	1	10. I mean, that's an enormous confidence value.
2	determinations as to what relative risks to	2	So there's not a lot of information from those ten
3	extract from those studies, correct?	3	people.
4	MS. BROWN: Objection to the form.	4	BY MS. PARFITT:
5	THE NUTBER OF THE 1 A 1 A 1		
	THE WITNESS: I I had to work with	5	Q And the reason I ask as well, as you
6	what they reported.	5 6	Q And the reason I ask as well, as you said earlier on in your deposition, you did not
6 7			
	what they reported. BY MS. PARFITT:	6	said earlier on in your deposition, you did not
7	what they reported.	6 7	said earlier on in your deposition, you did not know for all these studies their sample size.
7 8	what they reported. BY MS. PARFITT: Q Okay. And just like Hartge, they	6 7 8	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it,
7 8 9	what they reported. BY MS. PARFITT: Q Okay. And just like Hartge, they reported different pieces of information:	6 7 8 9	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it, but I've got all the studies, and it's a piece of
7 8 9 10	what they reported. BY MS. PARFITT: Q Okay. And just like Hartge, they reported different pieces of information: Diaphragms used, no diaphragm, all over, genital,	6 7 8 9 10	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it, but I've got all the studies, and it's a piece of cake, we can just go look at them and look at the
7 8 9 10 11	what they reported. BY MS. PARFITT: Q Okay. And just like Hartge, they reported different pieces of information: Diaphragms used, no diaphragm, all over, genital, legs, feet, correct?	6 7 8 9 10 11	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it, but I've got all the studies, and it's a piece of cake, we can just go look at them and look at the sample size. I didn't want to, like I didn't
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7 8 9 10 11 12 13	what they reported.  BY MS. PARFITT:  Q Okay. And just like Hartge, they reported different pieces of information:  Diaphragms used, no diaphragm, all over, genital, legs, feet, correct?  A Correct.  Q And you had to decide what was the most	6 7 8 9 10 11 12 13	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it, but I've got all the studies, and it's a piece of cake, we can just go look at them and look at the sample size. I didn't want to, like I didn't want to, like, make this is already a long enough report. I don't need to put every bit of
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7 8 9 10 11 12 13 14 15 16 17	what they reported. BY MS. PARFITT: Q Okay. And just like Hartge, they reported different pieces of information: Diaphragms used, no diaphragm, all over, genital, legs, feet, correct? A Correct. Q And you had to decide what was the most appropriate data to pull from those studies to include on your chart for relative risks, correct? A For the most MS. BROWN: Objection to the form. THE WITNESS: Yes, of course. BY MS. PARFITT:	6 7 8 9 10 11 12 13 14 15 16 17	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it, but I've got all the studies, and it's a piece of cake, we can just go look at them and look at the sample size. I didn't want to, like I didn't want to, like, make this is already a long enough report. I don't need to put every bit of data from every study in it to have it make sense to me.  Q So somewhere you have all the sample sizes pulled together for the various cases and controls for each one of these studies?  A It's in every one of the studies.
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	what they reported. BY MS. PARFITT:  Q Okay. And just like Hartge, they reported different pieces of information: Diaphragms used, no diaphragm, all over, genital, legs, feet, correct?  A Correct.  Q And you had to decide what was the most appropriate data to pull from those studies to include on your chart for relative risks, correct?  A For the most  MS. BROWN: Objection to the form.  THE WITNESS: Yes, of course.  BY MS. PARFITT:  Q Okay. So my question to you is, you chose for the Hartge, based upon that analysis, to use the any talc mentioned, which gave us a	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	said earlier on in your deposition, you did not know for all these studies their sample size.  A Oh, no, no, no. I didn't memorize it, but I've got all the studies, and it's a piece of cake, we can just go look at them and look at the sample size. I didn't want to, like I didn't want to, like, make this is already a long enough report. I don't need to put every bit of data from every study in it to have it make sense to me.  Q So somewhere you have all the sample sizes pulled together for the various cases and controls for each one of these studies?  A It's in every one of the studies.  Q I know it's in each and every one of the
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	Page 342		Page 344
1	A We can just look at the studies. If I	1	doesn't change anything about this exercise.
2	documented the sample size next to each one of	2	BY MS. PARFITT:
3	these, it wouldn't tell you why I picked this	3	Q Okay. Well, I didn't select Hartge.
4	particular relative risk.	4	You selected Hartge.
5	Q It would it would not offer valid	5	A Well, I selected it because it exists.
6	information as to the relevance of those relative	6	I mean, I my my goal was to find all the
7	risks?	7	studies that exist.
8	A Oh, my gosh. I mean if you were	8	Q Okay.
9	interested in it, I could find it for you. It	9	A I mean, I didn't invent it, right? I
10	wasn't it wasn't important for me to	10	just I just looked at
11	communicate what I was trying to communicate.	11	Q Well, I just didn't want the record to
12	Q No, I it's a different question.	12	reflect that I was selecting your data.
13	Is sample size important when one is	13	A No, but you it sounds like you would
14	doing an analysis of a scientific study?	14	prefer me to use that 2.5 from the ten people,
15	A Yeah, that's why it's in the paper.	15	instead of the 0.7 from the nearly hundred people.
16	Q Okay. Because if the sample size is too	16	Q I have
17	small, it may be underpowered; is that correct?	17	A And I'm happy to look at them both. I
18	MS. BROWN: Objection.	18	mean they both tell us some information. It's not
19	THE WITNESS: Well, I don't know. I	19	like, you know, one is ideal and the other isn't.
20	mean, if we're going to do power now, I think	20	But it really doesn't change the basic premise
21	that's going to be a different a different	21	here.
22	conversation.	22	Q All right. So on my chart I have them
23	The sample size being small can have all	23	both. I have 0.7 and 2.5. Do you see that?  A Um
24 25	kinds of all kinds of impact. This to me is actually the most generous way to look at these	25	
25	actually the most generous way to look at these	45	Q Right at the bottom there, "Genital use"
	Page 343		Page 345
1	Page 343 data, rather than picking at the same size. I	1	Page 345 and "Any talc use." Do you see that?
1 2		1 2	
	data, rather than picking at the same size. I		and "Any talc use." Do you see that?
2	data, rather than picking at the same size. I mean, I can do that too, right? I can say, This	2	and "Any talc use." Do you see that?  A I do.
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	Page 346		Page 348
1	A Correct.	1	to be hard for me to read it off of your figure
2	Q Yes. Okay.	2	because I don't know, like like, the Harlow and
3	Now, looking at the chart, which is 21,	3	Weiss one what is wrong with that one? Or is
4	what is the point estimate wait.	4	it
5	What I would like you to do, rather, I	5	MS. BROWN: That looks wrong, doesn't
6	would like you to circle the point estimate for	6	it?
7	every study that exceeds that has a 1.0.	7	THE WITNESS: No, it's Harlow and Weiss
8	MS. BROWN: Objection. Based on the	8	versus Harlow.
9	document you created as 21?	9	So what am I circling? I'm circling
10	MS. PARFITT: Which is identical to the	10	the the on the forest plot?
11	doctor's document, with the exception of I put two	11	BY MS. PARFITT:
12	numbers for Hartge.	12	Q On the forest plot, if you would be kind
13	MS. BROWN: You put two numbers for	13	enough to circle every relative risk where the
14	Moorman too.	14	point estimate was 1.0 or above.
15	MS. PARFITT: Before and after 2014,	15	A Oh, I did it wrong.
16	correct?	16	Q That's all right.
17	MS. BROWN: Nope, Moorman is 2009. You	17	A Sorry. I'm circling the ones that
18	have you've broken out Moorman by race.	18	are do you have another another copy of
19	MS. PARFITT: I did.	19	this?
20	MS. BROWN: So I mean, my point here is	20	MS. MILLER: You can have mine.
21	just if you wanted to use his report, he's happy	21	MR. LOCKE: I didn't
22	to answer your questions, but	22	MS. PARFITT: I'm sorry. I'm sorry,
23	MS. PARFITT: He did it but he did it	23	Tom?
24	too.	24	MR. LOCKE: I just couldn't hear you
25	MS. BROWN: Okay. That's fine.	25	trailed off at the end.
	Do go. 247		Dago 240
	Page 347	_	Page 349
1	MS. PARFITT: It's on his chart.	1	MS. PARFITT: Sure.
2	BY MS. PARFITT:	2	BY MS. PARFITT:
3	Q I didn't do anything the only	3	Q You have and maybe I can shorten this
4	modification I made to your chart, Doctor, is	4	for you, how about that, in the interest of time.
5	Hartge, and there I kept your 0.70 and added the	5	A Your call.
6	genital 2.5.	6	Q We have thank you. I appreciate
7	And what I'd like you to do is circle in	7	that.
8	that document every point estimate or odds ratio	8	We've got about 32 studies here. How
9	that is 1.0 or above.	9	many of those studies reflect an odds ratio
10	A 1.0 or higher?	10	greater than 1.0?
11	Q That's right.	11	MS. BROWN: For a relative risk?
12	MS. BROWN: Objection to the exercise.	12	MS. PARFITT: Correct.
13	And, Doctor, if you need the articles,	13	THE WITNESS: I don't know what to do
14	we'll give them to you.	14	with Moorman, because it's one study, right. Two
15	THE WITNESS: So just as an example, if	15	different odds ratios.
16	we look at Jordan 2007, which has an odds ratio of	16	BY MS. PARFITT:
17	1.00	17	Q Mm-hmm.
		1 10	A But it looks like above the dotted line,
18	BY MS. PARFITT:	18	
	Q Mm-hmm.	19	it's there's 24 studies, I guess, and then down
18	<ul><li>Q Mm-hmm.</li><li>A you find that one that would be</li></ul>	19 20	it's there's 24 studies, I guess, and then down below it, there's one, two, three, four,
18 19 20 21	Q Mm-hmm.  A you find that one that would be interesting for me to circle.	19	it's there's 24 studies, I guess, and then down below it, there's one, two, three, four, five there's 5 that are above 1.0, and you said
18 19 20	<ul><li>Q Mm-hmm.</li><li>A you find that one that would be</li></ul>	19 20	it's there's 24 studies, I guess, and then down below it, there's one, two, three, four, five there's 5 that are above 1.0, and you said above 1.0 this time, before you said
18 19 20 21	Q Mm-hmm. A you find that one that would be interesting for me to circle. Q If it has a 1.0, I'd like you to circle it.	19 20 21	it's there's 24 studies, I guess, and then down below it, there's one, two, three, four, five there's 5 that are above 1.0, and you said
18 19 20 21 22	<ul> <li>Q Mm-hmm.</li> <li>A you find that one that would be interesting for me to circle.</li> <li>Q If it has a 1.0, I'd like you to circle</li> </ul>	19 20 21 22	it's there's 24 studies, I guess, and then down below it, there's one, two, three, four, five there's 5 that are above 1.0, and you said above 1.0 this time, before you said

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	Page 350		Page 352
1	be	1	that those studies have a relative risk in excess
2	Q Right. So we're doing above 1.0.	2	of 1.0 demonstrate a positive result?
3	A Okay.	3	MS. BROWN: Objection to the form.
4	Q You pointed that out, and you're right.	4	THE WITNESS: So some some of those,
5	A Yeah. So have I done it? There's one,	5	yes, and some of those, no.
6	two, three, four well, I guess Hartge is	6	BY MS. PARFITT:
7	one, two, three, four, five	7	Q All right. Would it be fair to say that
8	Q Sure.	8	they're certainly trending above the null; is that
9	A there's five down below the dotted	9	correct?
10	line, and there were	10	MS. BROWN: Objection to the form.
11	Q Okay. And if you can just identify	11	THE WITNESS: Not necessarily. I'm just
12	those where the point estimate does not exceed	12	trying to imagine like I think I understand why
13	it's not above 1.0.	13	you're doing this but I'm just trying to
14	MS. BROWN: Counsel, can you represent,	14	imagine like standing in front of colleagues like
15	on the record, what this second up from the bottom	15	with the Tzonou one and say, I've decided that a
16	is?	16	relative risk of 1.05 is a positive risk.
17	MS. PARFITT: Sure. Hartge and Stewart,	17	I mean, you can only guess so close to
18	'94.	18	1.0. I mean, 1.0 is basically null, right?
19	MS. BROWN: Underneath that.	19	There's no there's no effect. So you can hope
20	MS. PARFITT: Wong.	20	for, but you're rarely going to get a 1.00. So if
21	MS. BROWN: No, above what is the	21	you get like a 1.01, 1.02, 1.03, those are
22	entry above Wong?	22	basically 1.0.
23	MS. PARFITT: Oh, in his table	23	I mean, you can you can say try to
24	THE WITNESS: Oh, that too.	24	make some point to somebody, Oh, it's a little bit
25	MS. PARFITT: In his table he had RR	25	above 1.0; therefore, it's a positive association.
	Mo.17114111. In mo duote ne mad rec		above no, increase, its a postave association.
	D 3F1		
	Page 351		Page 353
1	0.03, RR 0.05. It was just extracted from his	1	Page 353  But other than this setting, you're going to get
1 2		1 2	
	0.03, RR 0.05. It was just extracted from his		But other than this setting, you're going to get
2	0.03, RR 0.05. It was just extracted from his table.	2	But other than this setting, you're going to get laughed out of the room. I mean, this is this
2	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge	2 3	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it
2 3 4	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.	2 3 4	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive
2 3 4 5	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.	2 3 4 5	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.
2 3 4 5 6	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.  THE WITNESS: And so you want where just	2 3 4 5 6	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.  BY MS. PARFITT:
2 3 4 5 6 7	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.  THE WITNESS: And so you want where just the midpoint is above the number 1.0?	2 3 4 5 6 7	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.  BY MS. PARFITT:  Q Okay. Now, what I'd like you to do is
2 3 4 5 6 7 8	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.  THE WITNESS: And so you want where just the midpoint is above the number 1.0?  BY MS. PARFITT:	2 3 4 5 6 7 8	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.  BY MS. PARFITT:  Q Okay. Now, what I'd like you to do is look at the confidence intervals for each one of
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2 3 4 5 6 7 8 9 10	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.  THE WITNESS: And so you want where just the midpoint is above the number 1.0?  BY MS. PARFITT:  Q Correct.  A So Cramer, Harlow, Harlow, Chen, Cramer, Purdie, Chang, Cook, Green, Godard, Cramer, Ness,	2 3 4 5 6 7 8 9 10	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.  BY MS. PARFITT:  Q Okay. Now, what I'd like you to do is look at the confidence intervals for each one of those studies, and circle where the confidence interval shows a relative risk of 1.2.  MS. BROWN: Objection to the form of the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.  THE WITNESS: And so you want where just the midpoint is above the number 1.0?  BY MS. PARFITT:  Q Correct.  A So Cramer, Harlow, Harlow, Chen, Cramer, Purdie, Chang, Cook, Green, Godard, Cramer, Ness, Mills, Cramer, Gates, Merritt; the two odds ratios for Moorman, Wu, Rosenblatt, Kurta, Kotsopoulos, Wu, Cramer, Schildkraut; and then one of the two Hartge's, Whittemore  Q And are you circling those, Doctor?  A I'm not, no.  Q Okay. If you could do that because we'll attach it as an exhibit. Sorry.  A Should I just finish saying them  Q Sure.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.  BY MS. PARFITT:  Q Okay. Now, what I'd like you to do is look at the confidence intervals for each one of those studies, and circle where the confidence interval shows a relative risk of 1.2.  MS. BROWN: Objection to the form of the question.  BY MS. PARFITT:  Q And again, if you will just circle those.  A I I think you'd be better off drawing a line, right. Because it I mean, this scale here isn't really like there's no vertical scale that's labeled here. Right. So you've got 1.0, 1.1 and 1.2. I mean if you want, I think you ought to just take a ruler and run it up from 1.2.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	0.03, RR 0.05. It was just extracted from his table.  MS. BROWN: Oh, it's the second Hartge and Stewart.  MS. PARFITT: Yeah.  THE WITNESS: And so you want where just the midpoint is above the number 1.0?  BY MS. PARFITT:  Q Correct.  A So Cramer, Harlow, Harlow, Chen, Cramer, Purdie, Chang, Cook, Green, Godard, Cramer, Ness, Mills, Cramer, Gates, Merritt; the two odds ratios for Moorman, Wu, Rosenblatt, Kurta, Kotsopoulos, Wu, Cramer, Schildkraut; and then one of the two Hartge's, Whittemore  Q And are you circling those, Doctor?  A I'm not, no.  Q Okay. If you could do that because we'll attach it as an exhibit. Sorry.  A Should I just finish saying them  Q Sure.  A and then go back and do it?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	But other than this setting, you're going to get laughed out of the room. I mean, this is this is a 1.05. So, you know, that's you call it what you want. I don't call that a positive finding.  BY MS. PARFITT:  Q Okay. Now, what I'd like you to do is look at the confidence intervals for each one of those studies, and circle where the confidence interval shows a relative risk of 1.2.  MS. BROWN: Objection to the form of the question.  BY MS. PARFITT:  Q And again, if you will just circle those.  A I I think you'd be better off drawing a line, right. Because it I mean, this scale here isn't really like there's no vertical scale that's labeled here. Right. So you've got 1.0, 1.1 and 1.2. I mean if you want, I think you ought to just take a ruler and run it up from 1.2.  Q Why don't you just go ahead and identify

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	Page 354		Page 356
1	Q My question is just simply this: Would	1	was inconsistent.
2	you identify all studies where the confidence	2	Q And that aspect
3	interval is 1.2 or higher?	3	MS. BROWN: Are you looking at the
4	MS. BROWN: Objection to the form.	4	report?
5	BY MS. PARFITT:	5	THE WITNESS: Yeah.
6	Q And you can just circle them.	6	BY MS. PARFITT:
7	A And it doesn't have to mean anything to	7	Q was with regard to population study
8	me, right?	8	versus hospital-based studies?
9	Q Nope. Just circle anything where the	9	A Well, I think I made a comment about
10	confidence interval is above a 1.2.	10	both, right?
11	A So where the confidence interval	11	Q And if I can summarize your testimony,
12	includes 1.2?	12	but feel free to look, but your testimony from the
13	Q 1.2, correct.	13	report or your writings and your report suggest
14	A Or where it's above 1.2?	14	that the case-control studies are inconsistent,
15	Q It's above 1.2.	15	and you focus on the fact that the hospital-based
16	MS. BROWN: The entire interval?	16	controls were inconsistent with the population-
17	THE WITNESS: Well, so there's not many,	17	based controls.
18	right? So there's one	18	A That's one one of the areas of
19	BY MS. PARFITT:	19	inconsistency.
20	Q You understand that it includes 1.2?	20	Q Okay. And you base that opinion on the
21	A I heard oh, that's different,	21	fact that there the hospital-based studies were
22	because there's only one where it's above 1.2.	22	not statistically significant, but the
23	Q It includes the 1.2.	23	population-based studies were statistically
24	A Or two that are above it.	24	significant; is that correct?
25	So the two that are above it, don't	25	MS. BROWN: Objection to the form.
	Page 355		Page 357
1		1	
1 2	include it, right, so we got to start over.	1 2	THE WITNESS: That's one piece of
3	Q Everywhere sure. You go ahead and do it. Everywhere where the confidence interval is	3	evidence, right. So one piece of evidence is that the hospital-based ones, none of them were
4	above includes 1.2.	4	statistically significant, and some of the
5	A That's all right. I'm just going to put	5	population-based ones were.
6	a little asterisk next to them, because I already	6	BY MS. PARFITT:
7	made a mark	7	Q All right. And because you had some of
8	Q Sure, that's fine.	8	the population-based studies, you found
9	A next to the ones that are above 1.2.	9	inconsistent because the confidence intervals were
10	Okay.	10	not were such that they were not statistically
11	Q Okay. Let's go ahead and just put this	11	significant; is that correct?
12	here. I appreciate that.	12	A That's a
13	Okay. Here we go. Let's see here.	13	MS. BROWN: Objection to the form.
14	Okay. So let's just stay with that one	14	THE WITNESS: And as before, that's a
15	here for a moment. Let me give you give you a	15	piece of a piece of the information here.
16	blank one here for a moment. Is that all right?	16	BY MS. PARFITT:
17	So you have something in front of you.	17	Q Okay. I've reviewed your report. Other
	A Sure.	18	than the distinction between the statistical
1 Ω		19	significance of studies versus the nonstatistical
18 19			significance of studies, how else did you discern
19	Q Okay. All right.	20	SIZHILICANCE OF SHIGHES. HOW EISE OID VOIL DISCETTI
19 20	Dr. Diette, looking at the chart that we	20	
19 20 21	Dr. Diette, looking at the chart that we just talked about, you have described in your	21	that they were different and not consistent?
19 20 21 22	Dr. Diette, looking at the chart that we just talked about, you have described in your report that the case-control studies are	21 22	that they were different and not consistent?  A Well, I have a section on consistency.
19 20 21 22 23	Dr. Diette, looking at the chart that we just talked about, you have described in your report that the case-control studies are inconsistent. Is that your testimony?	21 22 23	that they were different and not consistent?  A Well, I have a section on consistency.  So it there's other things about these studies
19 20 21 22	Dr. Diette, looking at the chart that we just talked about, you have described in your report that the case-control studies are	21 22	that they were different and not consistent?  A Well, I have a section on consistency.

Page 358 Page 360 1 dose-response relationships are all over the 1 like that. So I'm -- that's more inconsistency. 2 place. So that I found to be an inconsistency. 2 Q Okay. Dr. Diette, what I'm trying to 3 The findings about certain kinds of ovarian 3 get at here is, the underbelly, I guess, of your 4 cancers, some showed a particular cell type and 4 opinions seem to be from your report that cohort 5 5 some -- some didn't. studies are inconsistent with the case-control 6 6 Let me just -studies, which they themselves are inconsistent 7 7 Q Let me ask you -because population-based studies and 8 8 hospital-based studies, some were statistically MS. BROWN: Wait, I don't think he's 9 finished. 9 significant and some were not. Correct? 10 10 A Exactly, yes. MS. PARFITT: No. Let's just make sure. 11 Q Okay. And that's really the -- the guts 11 THE WITNESS: I think we've said it, but I want to make it clear, right, because we were --12 of your report, correct? 12 13 MS. BROWN: Objection to the form. 13 we were really just sort of focused very -- very THE WITNESS: I -- no. I mean, those 14 14 much on population-based and hospital-based case 15 are two very important points, but I'd say there's 15 controls. 16 a heck of a lot more than that in the report. 16 BY MS. PARFITT: 17 BY MS. PARFITT: 17 Q That's right. 18 Q Okay. Did you go through -- let's --18 A But I think the fact that there is 19 let's talk a little bit about that. 19 basically, you know, not a signal from the cohort 20 You described these relative risks of 20 studies is an inconsistency with studies of 21 the case-control studies as small, weak -- small 21 another design, so another form of inconsistency. 22 and weak, correct? 22 I think that -- and what I've tried to 23 A Correct. 23 say here, right, because I think -- I think some 24 Q Okay. What type of -- those words 24 of these Hill criteria, it's hard to -- hard to 25 "small and weak," are those scientific words? 25 keep every -- every comment you want under one Page 359 Page 361 1 particular heading, and so I've tried to get at A So they're words that my colleagues and 1 2 this issue here too that if it were consistent 2 I use. I mean, it's a word that Dr. Rothman used 3 that talc caused or was associated with ovarian 3 when he did his analysis in 2000 and called the 4 cancer, I would expect to see it under a variety 4 summary odds ratio or the risk -- risk of 1.3, he 5 of circumstances, not just perineal dusting. And 5 called it weak. I'm not sure whether he's citing 6 6 so one of the inconsistencies is that, you know, a particular definition, but, you know, it --7 7 diaphragms and condoms, that we don't see that it's -- there's probably reasons, just like where signal. So I'm just saying that that's an 8 8 you talk about a p-value of 0.05 not being the 9 inconsistency. It's the opposite of consistency. 9 absolute line. I think it's why people have 10 And I guess too -- I mean just while 10 resisted trying to say that it has to be above an we're even still on the -- on the types of 11 11 exact specific number. 12 studies, I mean the Taher study that, I guess, you 12 But I think we can all recognize risks know, even though it's not published yet, I mean 13 13 that are large. You know, we know that a risk of 14 they've got a summary risk for the hospital-based 14 10 is a large risk. We know that 20 is a large 15 studies which is less than 1.0. Right. So now 15 risk. We know that a relative risk of 1.01, it's 16 it's not even just like -- if -- I don't know 16 got to be tiny, right, because it can't be any 17 whether we should like the Taher study or not, but 17 smaller than that on that particular scale. 18 it's out there, right. And so now we've got --18 So somewhere in there we have to use 19 Q It's out there. It's a piece of the 19 some judgment, and I think if you got a 1.2 or 20 evidence. 20 1.3, I don't know who -- I don't know who thinks 21 21 A Yeah, it's something that's out there, that's strong. It doesn't make any sense. 22 so now we've got something that's unpublished from 22 Q Do you agree that having a weak 23 2018 that's got not even a positive risk. I mean, 23 association does not rule out a causal connection? 24 this -- this exercise of going to look and see 24 MS. BROWN: Objection to the form. what's over 1.0, there's a 0.94 or 6 or something 25 25 THE WITNESS: Wait a minute, say it

	Page 362		Page 364
1	again because I think	1	Q Secondhand smoke and lung cancer.
2	BY MS. PARFITT:	2	MR. LOCKE: Objection.
3	Q Having a weak association would not rule	3	THE WITNESS: I think really the Surgeon
4	out a causal association.	4	General has put it at it's either about 1.7 or
5	A That's correct.	5	1.9, somewhere in there.
6	Q All right. Would you also agree that	6	BY MS. PARFITT:
7	while the strength of an association is a	7	Q Okay. Let me show you I'm sorry.
8	guideline for drawing an inference of causation,	8	1.7 or 1.9.
9	there is no specified threshold required?	9	Let me show you a study by Kim. And
10	MS. BROWN: Objection to the form.	10	it's entitled "Exposure to Secondhand Smoke and
11	THE WITNESS: I don't think there's a	11	the Risk of Cancer in Never Smokers." And I'll
12	specified threshold. I think it's a gradient,	12	represent that it's in the International Journal
13	right, that you have to use as you're applying	13	of Environment, 2018. And this would be a
14	your judgment about all of the evidence. And that	14	meta-analysis by Dr. Kim.
15	when you have a very small risk, you should be	15	A Do you know, is it something I cited or
16	more concerned about the distorting effects of	16	is this new new to me or
17	other factors, and if you have a larger risk, you	17	Q I did not see it in your
18	can be less worried about those distorting	18	A Okay. Thank you.
19	factors.	19	Q list of references.
20	BY MS. PARFITT:	20	In fact, good question. None of the 167
21	Q But you will agree with me under the	21	articles that were in your curriculum vitae did I
22	Bradford Hill factors, strong association or weak	22	see that you cited in support for your expert
23	association, neither are necessary for finding	23	report; is that correct?
24	causality, correct?	24	A That would I'm sure that's correct.
25	MS. BROWN: Objection to the form.	25	Q Okay. Okay. Do you see that?
	Page 363		5 265
	rage 303		Page 365
1		1	
1 2	THE WITNESS: So there isn't a single	1 2	A I do, yes.
2	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a	2	<ul><li>A I do, yes.</li><li>Q Okay. And if you look in the abstract,</li></ul>
2	THE WITNESS: So there isn't a single one of his considerations that all by itself is	2 3	A I do, yes.  Q Okay. And if you look in the abstract, do you see where the authors determined that the
2 3 4	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know,	2 3 4	A I do, yes.  Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung
2 3 4 5	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know, information about the studies. But he he	2 3 4 5	A I do, yes.  Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung cancer in never users was a relative risk rather
2 3 4 5 6	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know, information about the studies. But he he certainly does give us some guidance about what	2 3 4 5 6	A I do, yes.  Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung cancer in never users was a relative risk rather than of 1.2.
2 3 4 5 6 7	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know, information about the studies. But he he certainly does give us some guidance about what "strong" and "not strong" might mean and the	2 3 4 5 6 7	A I do, yes.  Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung cancer in never users was a relative risk rather than of 1.2.  Do you see that? Take a moment.
2 3 4 5 6 7 8	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know, information about the studies. But he he certainly does give us some guidance about what "strong" and "not strong" might mean and the implications of that.	2 3 4 5 6 7 8	A I do, yes.  Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung cancer in never users was a relative risk rather than of 1.2.  Do you see that? Take a moment. A Yeah.
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2 3 4 5 6 7 8 9 10 11	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know, information about the studies. But he he certainly does give us some guidance about what "strong" and "not strong" might mean and the implications of that.  BY MS. PARFITT:  Q But we can agree sitting here today that those general terms, "weak," "small," do not dictate whether or not there is causality.	2 3 4 5 6 7 8 9 10 11	A I do, yes. Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung cancer in never users was a relative risk rather than of 1.2. Do you see that? Take a moment. A Yeah. Q We'll put it on the ELMO. A So we're looking at the abstract? Q We are, mm-hmm. A And saying so odds ratio involving
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	THE WITNESS: So there isn't a single one of his considerations that all by itself is completely necessary, right. It's a it's a method to pull together a variety of, you know, information about the studies. But he he certainly does give us some guidance about what "strong" and "not strong" might mean and the implications of that.  BY MS. PARFITT:  Q But we can agree sitting here today that those general terms, "weak," "small," do not dictate whether or not there is causality.  MS. BROWN: Objection to the form.  THE WITNESS: They don't dictate it. They inform it.  BY MS. PARFITT:  Q You mentioned that the I want to come back to that one in a second.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A I do, yes. Q Okay. And if you look in the abstract, do you see where the authors determined that the relative risks for passive smoke exposure and lung cancer in never users was a relative risk rather than of 1.2.  Do you see that? Take a moment. A Yeah. Q We'll put it on the ELMO. A So we're looking at the abstract? Q We are, mm-hmm. A And saying so odds ratio involving never smokers with significant exposure to secondhand compared to never smokers was 1.163. Q Okay. Do you see where it says: "Passive smoke exposure and lung cancer in never users was a relative risk of 1.245"? And we can go ahead and circle that.
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Gregory B. Diette, M.D.

1 Q Okay. Let me show you as well the Lv study, and it was a 2015 study. "Risk of 2 programs to reduce secondhand smoke for 3 All-Cause Mortality Associated With Secondhand Smoke."  5 A Do I have that?  6 Q I'm getting that for you. Hold on one second.  8 A Oh, I'm sorry. I thought I — 8 The WITNESS: Oops, sorry.  10 A I thought I missed it. 10 (Diette Exhibit No. 23 was marked 12 for identification.) 12 they would use these risks to drive that or 14 or 14 or 14 throw what 14 the risk of 1.1 and 1.2 are very — are actually less than the relative risks that we seen with talcum powder products and ove cancer, correct?  10 A The last name, yeah. 20 A So all on the case-control structure of the results — 24 first sight — 25 Q That's right — 25 Q Correct. And they then report in the 28 A Yea, all though — exactly right, yep. 40 Qokay. Now, you yourself have do studies on indoor particulate matter, correct with that you do as well, correct? 21 A New Cornect and this is work that you do as well, correct? 22 A So the so seen with that you do as well, correct? 31 A Correct. 40 Qokay. Now, you yourself have do studies on indoor particulate matter, correct with the young down which — which particular one the Q All right. It's Common — it's Common Household Products, 2008." McCormack is article — author. 40 Q Research. And it's dated February 18 WR. PARFITT: 41 A Fervironmental Res, Environmental Tesearch. 40 United States and in other countries, there have been health programs implemented to reduce 2 the programs to reduce accencenthand smoke based upon relative risks for 12 programs to reduce accenthand smoke based upon relative risks, like 2 you've just seen, 1.1, 1.8, 1.2? 17 for identification.) 3 Programs to reduce secondhand 3 minute to 20 programs to a secondhand smoke based upon relative risks, like 3 programs to reduce accence. The programs to a Scord and the accent and this is sorrect. 40 programs to a secondhand smoke based upon relative risks, like 40 programs to a secondhand smoke based upon relative risks, l	age 368
2 study, and it was a 2015 study. "Risk of 3 All-Cause Mortality Associated With Secondhand 4 Smoke." 4 Smoke." 5 A Do I have that? 6 Q I'm getting that for you. Hold on one 7 second. 7 second. 7 second. 8 A Oh, I'm sorry. I thought I	e types of
4 Smoke."  A Do I have that?  6 Q I'm getting that for you. Hold on one 7 second.  8 A Oh, I'm sorry. I thought I 9 Q No, no worries.  9 Q No, no worries.  9 Q No, no worries.  10 A I thought I missed it.  11 (Diette Exhibit No. 23 was marked 11 thought I missed it.  12 for inputs they they used, and I don't I'm: 13 BY MS. PARFITT:  14 Q Do you have that in front of you? 15 A Yes. So this is by Lv? 16 Q That's right.  17 A The last name, yeah. 18 Q And now again, looking at the abstract 19 section, does it report the relative risk for 19 never smokers exposed to secondhand smoke versus 21 unexposed? 22 A So the pooled relative risk for never smokers exposed to secondhand smoke versus 23 smokers compared to those is that so that 24 first sentence of the results 25 Q That's right  Page 367  Page  A Correct.  Page 367  Page  A Correct.  Q Okay. Now, you yourself have do study with McCormack and Diette on common thousehold exposures?  A Yeah, although exactly right, yep, 6 Q Okay. Now, there have been and this is work that you do as well, correct?  MS. BROWN: Objection to the form. 9 BY MS. PARFITT: 9 DO Ayou do research work on secondhand 10 Q You do research work on secondhand 11 smoke? 12 A I have done, yeah, and still do. 13 Q Okay. And are you aware that in the use condhand smoke based upon relative risks, like 16 Cibette Exhibit No. 24 was marked 17 you've just seen, 1.1, 0.8, 1.2? 17 (Diette Exhibit No. 24 was marked 18 A So I don't know what input they would us these risks to drive that or input they would us these risks to drive that or input they would use these risks to drive that or input they would use these risks to drive that or input they would use these risks to drive that or input they would use these risks to drive that or input they would use these risks to drive that or input they would use these risks to drive that or input they would use these risks to drive that or input they wouldn't know what input don't know what input don't know what input they wouldn't know w	
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you've just seen, 1.1, 0.8, 1.2?	
J J	d
18 MR. LOCKE: Objection. 18 BY MS. PARFITT:	
THE WITNESS: I mean, I don't know if 19 Q Do you have that in front of you?	?
the programs were based on these studies, and 20 A I do.	
there certainly have been higher relative risks 21 Q Okay. Now, if you look at the first	
before. But I but I agree that there are page under the abstract, about the third line	
programs to reduce secondhand smoke exposure. 23 down excuse me, fourth line down, it says	ays:
24 BY MS. PARFITT: 24 "There is a public health imperative to	
25 Q Okay. And would you agree today that 25 characterize indoor source as being less	

93 (Pages 366 to 369)

	Page 370		Page 372
1	extensively characterized" excuse me. I'm	1	MS. BROWN: Objection to the form. You
2	sorry.	2	need the disease to link the
3	"There is a public health imperative to	3	MS. PARFITT: Lung. Lung.
4	characterize indoor sources of PM" I assume	4	MS. BROWN: You mean cancer? Objection
5	that's particulate matter?	5	to the form.
6	A Correct.	6	THE WITNESS: Anyway, I can't answer it.
7	Q "with this vulnerable population to	7	You need more in the sentence or the question in
8	enable effective intervention strategies."	8	order for me to be able to answer it.
9	Did I read that correctly?	9	BY MS. PARFITT:
10	A You did.	10	Q Okay. Are there any fair enough.
11	Q Okay. You were the lead one of the	11	Are there any reported relative risks
12	lead authors in that study?	12	between indoor particulate matter and lung
13	A Yeah, I was, by position, the senior	13	disease?
14	author, but I was the head of the the study	14	MS. BROWN: Objection to the form.
15	that produced this paper.	15	THE WITNESS: I'd want to be super
16	Q All right. And what is and do you	16	careful about what we're saying is lung disease,
17	have an opinion with regard to what the relative	17	because some people might think that that means
18	risks are for indoor ambient particulate matter?	18	the risk of developing a particular lung disease,
19	A For what?	19	and others might mean the worsening of an existing
20	Q For	20	disease or a lung function abnormality.
21	A You mean qualitative, like what	21	BY MS. PARFITT:
22	illnesses they cause or	22	Q Okay. Do you know what the relative
23	Q Yes, with regard I believe you	23	risk is between indoor particulate matter and
24	studied a bit of asthma, so I believe it would be	24	asthma?
25	the relative risk of indoor particulates and	25	A The risk of developing asthma?
	Page 371		Page 373
1	asthma?	1	Q Correct.
2	A Well, there's not one single way to		
3		1 2	A It's not
3		2 3	A It's not MS. BROWN: Objection to the form.
	answer that, right. So this this paper doesn't	3	MS. BROWN: Objection to the form.
4	answer that, right. So this this paper doesn't look like the one that's actually quantified it,	3 4	MS. BROWN: Objection to the form. THE WITNESS: Sorry. It's not known.
4 5	answer that, right. So this this paper doesn't look like the one that's actually quantified it, right. We have other ones that look at the	3 4 5	MS. BROWN: Objection to the form. THE WITNESS: Sorry. It's not known. BY MS. PARFITT:
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4 5 6 7	answer that, right. So this this paper doesn't look like the one that's actually quantified it, right. We have other ones that look at the increase in, say, symptoms, for example, or exacerbations per very small increment in	3 4 5 6 7	MS. BROWN: Objection to the form. THE WITNESS: Sorry. It's not known. BY MS. PARFITT: Q It's not known. A Not known.
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	Page 374		Page 376
1	But as of this point, I think we should I	1	meter cubed. It may be from a particular source,
2	explain or just	2	like traffic-related pollution or not.
3	BY MS. PARFITT:	3	I mean there's more to it. There's not
4	Q No, I all I really want to know in	4	just like some summary that that I can I can
5	the interest of time is whether or not you have	5	make. Maybe you can find somebody that can just
6	reviewed any of the scientific literature data	6	say particulate matter has this risk of causing
7	that reports what the relative risk is for indoor	7	asthma. I haven't seen it.
8	particulate matter and the risk of getting asthma?	8	But it's not there aren't like a whole
9	MS. BROWN: Objection to the form.	9	bunch of studies looking at the relationship
10	BY MS. PARFITT:	10	between indoor and outdoor particulate matter and
11	Q And if you haven't, that's fine.	11	lung disease as both, you know, developing newly
12	A Oh, my gosh, no, it's not that. I have.	12	and worsening the existing ones.
13	I just don't think that you can answer that	13	BY MS. PARFITT:
14	question. I'm not saying there's not some study	14	Q Right. Does secondhand smoke cause lung
15	out there that may estimate a risk for that, but	15	cancer?
16	it isn't established. Like, at this point, we	16	MS. BROWN: Objection to the form.
17	cannot say in 2019 that indoor particulate matter	17	THE WITNESS: It seems it seems that
18	causes asthma.	18	that that has been established.
19	And and you have to say more to the	19	(Counsel conferring.)
20	sentence. So let's just talk about like adults	20	BY MS. PARFITT:
21	living in the city. We can't say that. You	21	Q Okay. Let's talk a little bit
22	know you know, there's there's studies that	22	THE WITNESS: We're just doing a time
23	have looked at the relative risk of indoor	23	check. I'm just trying do you know roughly how
24	cooking, which is predominantly particulate	24	much we
25	matter, in developing countries, but even the	25	THE VIDEOGRAPHER: Five hours, 34
	Page 375		Page 377
1		1	Page 377 minutes.
1 2	Page 375 asthma evidence is not fully developed. So it's just it's one of those things	1 2	
	asthma evidence is not fully developed.	1	minutes.
2	asthma evidence is not fully developed. So it's just it's one of those things	2	minutes.  THE WITNESS: So a little under an hour
2	asthma evidence is not fully developed.  So it's just it's one of those things where you may find a paper that has an estimate,	2 3	minutes.  THE WITNESS: So a little under an hour and a half? Did you guys want to do a
2 3 4	asthma evidence is not fully developed.  So it's just it's one of those things where you may find a paper that has an estimate, but it hasn't been fully established yet.	2 3 4	minutes.  THE WITNESS: So a little under an hour and a half? Did you guys want to do a  MS. PARFITT: A quick break here? Sure.
2 3 4 5	asthma evidence is not fully developed.  So it's just it's one of those things where you may find a paper that has an estimate, but it hasn't been fully established yet.  Q All right. Do you I understand it's	2 3 4 5	minutes.  THE WITNESS: So a little under an hour and a half? Did you guys want to do a  MS. PARFITT: A quick break here? Sure.  THE WITNESS: or a break here or
2 3 4 5 6	asthma evidence is not fully developed.  So it's just it's one of those things where you may find a paper that has an estimate, but it hasn't been fully established yet.  Q All right. Do you I understand it's not fully established, but are there reported relative risks from the scientific literature?	2 3 4 5 6	minutes.  THE WITNESS: So a little under an hour and a half? Did you guys want to do a  MS. PARFITT: A quick break here? Sure.  THE WITNESS: or a break here or wait?
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	Page 378		Page 380
1	smoke and and lung cancer.	1	Q That's all right.
2	And what I would like you to do is	2	is related to secondhand smoke and
3	and I apologize, I don't have copies of this so	3	lung cancer?
4	I'm showing you what is the report of the Surgeon	4	MS. BROWN: Objection to the form.
5	General, I believe it was back in 2006, "The	5	THE WITNESS: It looks like it there. I
6	Health Consequences of Involuntary Exposure to	6	remember there's other numbers in there as well,
7	Tobacco Smoke, A Report of the Surgeon General."	7	but I mean, I remember it being 1-point something
8	Have you read that in the past?	8	and
9	A So definitely not every word, but I've	9	BY MS. PARFITT:
10	read big chunks of it.	10	Q Does that refresh my memory?
11	Q Okay. I figured with your work you may	11	MS. BROWN: Well, let him finish,
12	have.	12	please.
13	A Yeah.	13	THE WITNESS: I think there's somewhere
14	Q All right. Let me direct your attention	14	else in there where there's other estimates, but
15	to	15	still not like not sky high. Still less than
16	MS. PARFITT: And I apologize to all, so	16	2.0.
17	you have to look on the camera on the screen.	17	BY MS. PARFITT:
18	MS. BROWN: Okay. So just for the	18	Q But you don't disagree with the Surgeon
19	record, we don't have copies of this, and so I	19	General's conclusion that the pooled evidence
20	will object to the fact that we have no context or	20	indicates a 20 to 30 percent increase in the risk
21	ability to look at the document ourselves.	21	of lung cancer from secondhand smoke exposure
22	MS. PARFITT: All right.	22	associated with living with a smoker, correct?
23	BY MS. PARFITT: All right.	23	MR. LOCKE: Objection.
24	Q And again, Doctor, you've reviewed this	24	MS. BROWN: Objection. He doesn't have
25	report, correct, in the past?	25	the document, he can't review it.
23	report, correct, in the past:	25	the document, he can't review it.
	Page 379		Page 381
1	A In the past, and I've read parts of it,	1	BY MS. PARFITT:
2	but as you know, I mean it's a humongous	2	Q Are you disputing that conclusion?
3	Q It is big.	3	MS. BROWN: Objection. He has no basis
4	A document, and so some parts	4	to do it, he doesn't have the document.
5	weren't weren't for me.	5	BY MS. PARFITT:
6	Q All right. I want to focus your		
		6	Q Are you disputing that, Doctor?
7	attention on the conclusions of the Surgeon	6 7	<ul><li>Q Are you disputing that, Doctor?</li><li>A I would</li></ul>
7 8			
	attention on the conclusions of the Surgeon	7	A I would
8	attention on the conclusions of the Surgeon General's report.	7 8	A I would MR. LOCKE: Objection.
8 9	attention on the conclusions of the Surgeon General's report.  And 1: "The evidence is sufficient to infer a causal relationship between secondhand	7 8 9	A I would MR. LOCKE: Objection. THE WITNESS: I would say it fits with what I understood to be true at the time that that
8 9 10	attention on the conclusions of the Surgeon General's report.  And 1: "The evidence is sufficient to	7 8 9 10	A I would MR. LOCKE: Objection. THE WITNESS: I would say it fits with
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	attention on the conclusions of the Surgeon General's report.  And 1: "The evidence is sufficient to infer a causal relationship between secondhand smoke exposure and lung cancer among lifetime nonsmokers. This conclusion extends to all secondhand smoke exposure, regardless of location.  "2. The pooled evidence that indicates" sorry "the pooled evidence indicates a 20 to 30 percent" that would be a 1.2 or 1.3 relative risk "increase in the risk of lung cancer from secondhand smoke exposure associated with a smoker."  Did I read that correctly?  A You did.  Q And is that what the are those the numbers, 1.2 and 1.3, the relative risks that the	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A I would MR. LOCKE: Objection. THE WITNESS: I would say it fits with what I understood to be true at the time that that was published. BY MS. PARFITT: Q Fair enough. Thank you. I appreciate that. Dr. Diette, is it fair that to say that we don't have, and you've not reviewed, any Johnson Johnson & Johnson specific epidemiology with regard to a study of just Johnson & Johnson Baby Powder? MS. BROWN: Objection to the form. THE WITNESS: That is correct. BY MS. PARFITT: Q Okay. And so what we rely on, and what

	Page 382		Page 384
1	correct?	1	BY MS. PARFITT:
2	MS. BROWN: Objection to the form.	2	Q Okay. When you say it doesn't change
3	MR. LOCKE: Objection.	3	the totality of the evidence that we have
4	THE WITNESS: I I wouldn't	4	available for us, isn't it true that the presence
5	characterize it exactly that way. I mean I would	5	of a carcinogen, like asbestos in talcum powder
6	say that I can't really sort between different	6	products, supports the biological biologically
7	brands based on the epidemiologic literature, but	7	plausible mechanism for association between talcum
8	whatever all brands is, I don't you know, I	8	powder products and ovarian cancer?
9	don't know what that represents.	9	MS. BROWN: Objection to the form of the
10	BY MS. PARFITT:	10	question.
11	Q And would it be fair then if one product	11	THE WITNESS: I I'd say no. And for
12	that contained one product, talcum powder	12	reasons, if you want them, or just leave it at no.
13	product contained asbestos, and another did not,	13	BY MS. PARFITT:
14	that would result in a conclusion that would draw	14	Q Well, you've testified that asbestos is
15	it towards the null? Is that fair?	15	a carcinogen. Correct?
16	MS. BROWN: Objection to the question.	16	A Correct.
17	THE WITNESS: I don't understand that.	17	Q All right. And the fact that asbestos
18	BY MS. PARFITT:	18	might be in the talcum powder product does not
19	Q Okay.	19	impact your opinions with regard to the increased
20	A I mean I understand the idea of drawing	20	biologically plausible mechanism for talc to cause
21	something to the null. I just don't understand	21	ovarian cancer.
22	Q Sure.	22	MS. BROWN: Objection to the form. Are
23	A what preceded that.	23	you talking about a Johnson & Johnson product?
24	Q If you have a product like Johnson &	24	MS. PARFITT: Just generally.
25	Johnson, and you and it has a carcinogen in it,	25	MS. BROWN: Objection to the form.
		23	MS. BRO WIV. Objection to the form.
	Page 383		Page 385
1	and you lump it together with other products that	1	THE WITNESS: It it does not.
2	are not infected or contaminated with asbestos,	l .	4 4 4 7 7
2		2	As you ask these things, I'm trying to
3	what does that do to the overall relative risk	3	As you ask these things, I'm trying to figure out if I'm supposed to explain what I'm
4	what does that do to the overall relative risk A Oh.		· · · · · · · · · · · · · · · · · · ·
		3	figure out if I'm supposed to explain what I'm
4	A Oh.	3 4	figure out if I'm supposed to explain what I'm saying or is
4 5	<ul><li>A Oh.</li><li>Q when studying that product?</li></ul>	3 4 5	figure out if I'm supposed to explain what I'm saying or is MS. BROWN: No, you answered the
4 5 6	<ul><li>A Oh.</li><li>Q when studying that product?</li><li>MS. BROWN: Objection to the incomplete</li></ul>	3 4 5 6	figure out if I'm supposed to explain what I'm saying or is MS. BROWN: No, you answered the question.
4 5 6 7	A Oh. Q when studying that product? MS. BROWN: Objection to the incomplete hypothetical.	3 4 5 6 7	figure out if I'm supposed to explain what I'm saying or is MS. BROWN: No, you answered the question. THE WITNESS: Okay.
4 5 6 7 8	A Oh. Q when studying that product? MS. BROWN: Objection to the incomplete hypothetical. THE WITNESS: So concept and reality,	3 4 5 6 7 8	figure out if I'm supposed to explain what I'm saying or is MS. BROWN: No, you answered the question. THE WITNESS: Okay. MS. BROWN: She'll ask you another one
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4 5 6 7 8 9 10 11	A Oh. Q when studying that product? MS. BROWN: Objection to the incomplete hypothetical. THE WITNESS: So concept and reality, right. So the concept would be, if you knew that there were enough asbestos that led to an exposure that was enough in order to cause a disease from one product, and it was pooled with another	3 4 5 6 7 8 9 10 11	figure out if I'm supposed to explain what I'm saying or is MS. BROWN: No, you answered the question. THE WITNESS: Okay. MS. BROWN: She'll ask you another one if she has one. THE WITNESS: Okay. All right. BY MS. PARFITT: Q Does Johnson & Johnson sell baby powder that's 99 percent asbestos and 1 percent
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Gregory B. Diette, M.D.

Page 388 Page 386 THE WITNESS: No, there's not enough 1 1 And then I think if you -- if you pair 2 information in what you said there. 2 that with more modern studies, if you take like 3 BY MS. PARFITT: 3 the Reid study from Australia, you take women who 4 4 worked, you know, in and around a crocidolite Q What would you need? 5 5 A So I would need a couple of things. One mine, they certainly had enough exposure to get 6 is I would need to have some estimate of what the 6 asbestos-related diseases, but they don't get 7 7 dose would be, and some assurance from somewhere. ovarian cancer. 8 which I don't have, that that represented a dose 8 And so I think that the -- you know, the 9 that was sufficient to cause -- and by dose, I'm 9 sum total of all that just -- it doesn't make 10 10 talking about dose of asbestos, right -- that that sense that just knowing the fact that there's some 11 11 was a sufficient dose to cause ovarian cancer. particle -- even if it's true, that some particle 12 12 of asbestos is going to be enough to cause And based on what I've seen, I can't 13 13 make that link. I can't -- I haven't seen disease. anything that says that there's a plausible 14 Q Okay. Have you -- have you read -- I 14 15 concentration or dose that people would be exposed 15 didn't see it in your reliance list -- Reid, 2012? 16 16 to that links to anything I can find in the A I have two Reeds, I think, and if I only 17 17 epidemiologic literature about how much, if any, listed one, I meant to include two. 18 it would take in order to -- to cause ovarian 18 Q Yeah, you only listed 2011 Reid. You cancer. And what I -- should I finish? didn't list 2012 Reid. 19 19 20 Q Mm-hmm, yeah, finish. 20 A I meant -- so I don't know which one is 21 21 A Okay. I'm sorry. there. There's one from Whitnum, which is the 22 22 Q I'm trying not to interpret you. study of the women that -- you know, that I was 23 23 A No, no, you're not. I didn't mean -- I just describing, and a separate one is -- it's 24 basic -- basically like a meta-analysis or a 2.4 didn't think you were. 25 25 Q So doing better. reanalysis of the ovarian cancer and asbestos Page 387 Page 389 1 A I didn't think you were. 1 literature. 2 So I mean there's more, right. I mean 2 Q Okay. Do you recall from your reading 3 so the -- if you look at IARC and what those 3 that the scientists in Reid 2012 determined that 4 studies represented, they represent for the most 4 childhood exposure to asbestos was associated with 5 part -- and by IARC, I'm talking about IARC and 5 an increased risk of cancer mortality which was 6 6 ovarian cancer and asbestos -- you know, mostly 3.5 times greater than the general population? Do 7 7 circumstances that aren't typical of American you recall those numbers? 8 A I don't, but cancer mortality to -women. For example, so women in Europe who were 8 9 working at a time and place when there was 9 MS. BROWN: Objection. 10 different forms and lots of asbestos that may have 10 THE WITNESS: Can you tell me which -been sufficient to cause other asbestos-related because I don't remember which year links to which 11 11 12 diseases. 12 Reid study. 13 So if you -- if those -- if those 13 BY MS. PARFITT: 14 findings are absolutely accurate -- you know, you 14 Q That was the 2012 that I was speaking 15 take away the issue of misclassification or 15 of. 16 anything else -- if they're absolutely accurate, 16 A No, I understand that. I heard the 17 you've got a relative risk in the neighborhood of 17 year, but I don't know what the title is. 18 like 1.75 or something like that. 18 Q Oh, the title is "All-cause mortality in 19 19 So I'm not saying that's not an cancer incidence among adults exposed to blue 20 20 asbestos during childhood." important risk, but it's not a huge risk, right? 21 21 So we're taking heavy industrial exposure to get A I think that's a third study then, 22 to a 1.75. I haven't seen anything that could 22 because I think the two I'm referring to are --23 tell me that anything we're talking about here 23 are two different ones. 24 could possibly rise to the level of heavy 24 Q All right. So did you read the 2012 or 25 industrial exposure. 25 that just wasn't one you read?

98 (Pages 386 to 389)

	Page 390		Page 392
1	MS. BROWN: Well, Counsel, can you show	1	THE WITNESS: I'm not disagreeing with
2	it to him and he'll tell you?	2	you, I think that's the language they use, but
3	MS. PARFITT: Sure.	3	they they used their their strongest
4	THE WITNESS: I don't know if either of	4	their strongest grading.
5	the ones that I cite, you know, that I'm familiar	5	BY MS. PARFITT:
6	with are from 2012, but I don't think I read the	6	Q How many of the IARC studies that formed
7	one that you're talking about.	7	the basis for IARC's conclusion that asbestos
8	BY MS. PARFITT:	8	causes ovarian cancer was there information
9	Q Okay. From looking at your curriculum	9	concerning the exposure and the dose?
10	vitae and the studies you cited, you cited Reid	10	A So I think you said something that you
11	actually you cited three Reids. You cited Reid	11	didn't mean to, because I think you said how many
12	2011, you cited Reid 2008, and you cited Reid	12	of the IARC studies that IARC considered. I
13	2009. The study that you did not cite was Reid	13	think did you mean how many of the underlying
14	2012.	14	studies that IARC considered?
15	A That that sounds believable. That	15	Q Correct.
16	makes sense.	16	A Okay. And so there's at least five that
17	Q All right. So for purposes of the	17	I remember that were like sort of factory worker
18	opinions in your report, you did not rely on Reid	18	type studies, and then I think there were a couple
19	2012, is that fair?	19	of more. I'd have to go back, though, to look and
20	MS. BROWN: Objection to the form of the	20	see what what they had about dose, if anything.
21	question.	21	My I'm thinking like at least for the World
22	THE WITNESS: I I don't think I'm	22	War II era ones, they probably didn't have good
23	familiar with that study.	23	measures at all, you know, if any.
24	BY MS. PARFITT:	24	Q Okay. Let me show you what I will have
25	Q Okay. Fair enough.	25	marked as Exhibit 27.
	Page 391		D 202
	5		Page 393
1	Are you able to share with us,	1	(Diette Exhibit No. 27 was marked
1 2		1 2	_
	Are you able to share with us,		(Diette Exhibit No. 27 was marked
2	Are you able to share with us, Dr. Diette, what the minimum dose of asbestos is	2	(Diette Exhibit No. 27 was marked for identification.)
2	Are you able to share with us, Dr. Diette, what the minimum dose of asbestos is necessary in order to cause an ovarian cancer?	2 3	(Diette Exhibit No. 27 was marked for identification.) MR. ROSEN: 26, for the record, is the
2 3 4	Are you able to share with us, Dr. Diette, what the minimum dose of asbestos is necessary in order to cause an ovarian cancer? MS. BROWN: Objection to the form of the	2 3 4	(Diette Exhibit No. 27 was marked for identification.)  MR. ROSEN: 26, for the record, is the Surgeon General's report, which we'll supplement
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99 (Pages 390 to 393)

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Gregory B. Diette, M.D.

	Page 394		Page 396
1	examination of the association between asbestos	1	Q Okay. Do you see where the working
2	and ovarian cancer was not undertaken by the IOM,"	2	group of IARC considered all of the data, and they
3	and then it has a 2000 a 2006 date. Correct?	3	made a determination that there were not, at the
4	A Yes.	4	bottom, sufficient they ruled out the
5	Q Okay. Now, before we get to Table 2.8,	5	possibility that there may have been a
6	what I want you to do is turn over to page 256.	6	misdiagnosis.
7	All right. And again, directing your	7	Do you see that?
8	attention to the far right column. Are you there?	8	MS. BROWN: Objection to the form.
9	And it starts with, "Working group"?	9	THE WITNESS: I see that they've that
10	A I am. I'm sorry, I'm distracted because	10	they reached that that conclusion.
11	I think there's	11	BY MS. PARFITT:
12	MS. BROWN: It has a weird	12	Q Okay. And that's different than the
13	THE WITNESS: there's like a font	13	conclusion you raised in your report, correct?
14	issue or something, like somebody's printer didn't	14	A Well, it's different
15	have the right	15	MS. BROWN: Objection.
16	BY MS. PARFITT:	16	THE WITNESS: It is different, yes.
17	Q That might have been ours. I apologize.	17	BY MS. PARFITT:
18	Not ideal circumstances.	18	Q All okay. Right. Let's go back to
19	All right. Do you see where it says,	19	again page 253.
20	"The working group"?	20	And you will see it references a table,
21	A I do.	21	Table 2.8. Do you see that on the top of 254?
22	Q All right. "The working group noted	22	A Okay.
23	that a causal association between exposure to	23	Q Okay. Got that.
24	asbestos and cancer of the ovary was clearly	24	Okay. Let me show you what we'll have
7.4			
25	established based on five strongly positive cohort	25	marked as Exhibit 28.
	established based on five strongly positive cohort		marked as Exhibit 28.
25	established based on five strongly positive cohort  Page 395	25	marked as Exhibit 28.  Page 397
25	established based on five strongly positive cohort  Page 395  mortality studies of women with heavy occupational	25 1	marked as Exhibit 28.  Page 397  (Diette Exhibit No. 28 was marked
25 1 2	established based on five strongly positive cohort  Page 395  mortality studies of women with heavy occupational exposure to asbestos."	25 1 2	marked as Exhibit 28.  Page 397  (Diette Exhibit No. 28 was marked for identification.)
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100 (Pages 394 to 397)

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	Page 398		Page 400
1	risk for ovarian cancer and lung cancer, for	1	BY MS. PARFITT:
2	ovarian cancer it was 2.75, and for lung cancer it	2	Q Sure.
3	was 2.41. Do you see that?	3	A In one of your questions a little while
4	A I do.	4	back, you were asking me to agree that you were
5	Q Okay. Then move down to the Wignall and	5	reading fine, and you were for the relative risks.
6	Fox study. It's a 1982 study. Do you see that?	6	Q Yeah.
7	A I don't oh, yeah, the next one down,	7	A None of these are relative risks,
8	yeah.	8	though. They're SMRs and SIRs. So just a
9	Q Okay, yeah. Do you see that the	9	slightly different
10	relative risk for ovarian cancer were 2.13, and	10	Q I appreciate that. Thank you. Thank
11	for lung cancer 2.73?	11	you for the correction. Thank you.
12	A Correct.	12	Next question. Do you intend to give an
13	Q And let's move down to Pira in 2005. Do	13	opinion that fibrous tale is a carcinogen?
14	you see where the relative risk for ovarian cancer	14	MS. BROWN: Form.
15	were 2.61 and for lung cancer 2.82?	15	THE WITNESS: I'm not sure I understand
16	A I do.	16	what fibrous tale is.
17	Q All right. And then let's move to	17	BY MS. PARFITT:
18	Magnani, a 2008 study.	18	Q Okay. Let me direct your attention
19	All right. Do you see and this is	19	to we'll go back to the IARC on ovarian
20	one of the studies that the working group of IARC	20	cancer or, excuse me, IARC on asbestos.
21	looked at. They determined that the relative risk	21	Paragraph 1.1 on page 219.
22	for not determined they indicated that the	22	Are you there?
23	relative risk for ovarian cancer on the Magnani	23	A Paragraph 1, yes.
24	study was 2.27, and for lung cancer 2.20.	24	Q Yes. Okay. Do you see where after it
25	Do you see that?	25	has IARC, '73, and USGS, 2001, it states: "The
	Page 399		Page 401
1	A I do.	1	conclusions reached in this monograph about
2	Q All right. And let's go on to the	2	asbestos and its carcinogenic risks apply to these
3	Ferrante study. Do you see that?	3	six types of fibres wherever they are found, and
4	MS. BROWN: Where where are you?	4	that includes talc containing asbestiform fibres."
5	MS. PARFITT: On the last page.	5	Do you see that?
6	BY MS. PARFITT:	6	A Yes.
7	Q Do you see that? It's on the last page,	7	Q All right. Do you intend to give an
8	Ferrante, 2007. Do you see that?	8	opinion in this case that talc containing
9	A I do.	9	asbestiform fibers can cause ovarian cancer?
10	Q Okay. And the relative risk for ovarian	10	MS. BROWN: Objection to the form.
11	cancer was 1.43, and for lung cancer it was 1.17.	11	That's different than the original question.
12	Now I'll represent to you Doctor	1 12	MS. PARFILL: IIIS.
12 13	Now, I'll represent to you, Doctor or, Dr. Diette, is it fair to say that this	12 13	MS. PARFITT: It is.  MS. BROWN: Did you mean it to be?
13	or, Dr. Diette, is it fair to say that this	13	MS. BROWN: Did you mean it to be?
13 14	or, Dr. Diette, is it fair to say that this Table 2.8 of epidemiological exposures, asbestos	13 14	MS. BROWN: Did you mean it to be? MS. PARFITT: No. I mean the new
13 14 15	or, Dr. Diette, is it fair to say that this Table 2.8 of epidemiological exposures, asbestos exposure and ovarian cancer formed part of the	13 14 15	MS. BROWN: Did you mean it to be? MS. PARFITT: No. I mean the new question.
13 14 15 16	or, Dr. Diette, is it fair to say that this Table 2.8 of epidemiological exposures, asbestos exposure and ovarian cancer formed part of the bases for IARC's decision in their IARC report	13 14 15 16	MS. BROWN: Did you mean it to be? MS. PARFITT: No. I mean the new question. MS. BROWN: Okay.
13 14 15 16 17	or, Dr. Diette, is it fair to say that this Table 2.8 of epidemiological exposures, asbestos exposure and ovarian cancer formed part of the bases for IARC's decision in their IARC report that asbestos or ovarian asbestos causes	13 14 15 16 17	MS. BROWN: Did you mean it to be? MS. PARFITT: No. I mean the new question. MS. BROWN: Okay. THE WITNESS: So, because to me, the wa
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13 14 15 16 17 18 19 20 21 22 23	or, Dr. Diette, is it fair to say that this Table 2.8 of epidemiological exposures, asbestos exposure and ovarian cancer formed part of the bases for IARC's decision in their IARC report that asbestos or ovarian asbestos causes ovarian cancer?  A I assume so, yeah. Q Okay. All right. Let's talk a little bit do you intend to give an opinion in this case that fibrous talc is a carcinogen? MS. BROWN: Objection to the form.	13 14 15 16 17 18 19 20 21 22 23	MS. BROWN: Did you mean it to be?  MS. PARFITT: No. I mean the new question.  MS. BROWN: Okay.  THE WITNESS: So, because to me, the wa I have read this before and then also again now, I think, although I can't know what they were intending, but this to me says basically talc with asbestos in it what we would agree is talc with asbestos in it, as opposed to something else.  And I don't think you need the "talc
13 14 15 16 17 18 19 20 21 22	or, Dr. Diette, is it fair to say that this Table 2.8 of epidemiological exposures, asbestos exposure and ovarian cancer formed part of the bases for IARC's decision in their IARC report that asbestos or ovarian asbestos causes ovarian cancer?  A I assume so, yeah. Q Okay. All right. Let's talk a little bit do you intend to give an opinion in this case that fibrous talc is a carcinogen?	13 14 15 16 17 18 19 20 21 22	MS. BROWN: Did you mean it to be? MS. PARFITT: No. I mean the new question. MS. BROWN: Okay. THE WITNESS: So, because to me, the wa I have read this before and then also again now, I think, although I can't know what they were intending, but this to me says basically talc with asbestos in it what we would agree is talc with asbestos in it, as opposed to something else.

	Page 402		Page 404
1	increase carcinogenic risk if there's enough of a	1	sufficient dose. It's not a measurement of dose.
2	dose.	2	It's an indicator of sufficient sufficient
3	BY MS. PARFITT:	3	exposure to be linkable to things like lung
4	Q Okay. Did you see anywhere in the IARC	4	cancer.
5	working group document that we've been talking	5	The same kind of question for being
6	about that the working group determined that there	6	around coworkers, and so a yes/no to that has been
7	was a causal association between asbestos and	7	sufficient.
8	ovarian cancer, but it depended on the dose?	8	In our other studies, we we get more
9	MR. LOCKE: Objection.	9	precise so that we'll and use a variety of
10	MS. BROWN: Objection to the form of the	10	overlapping methods. So one is to to query
11	question.	11	if it's a child study, to query the parent about
12	THE WITNESS: I don't recall.	12	the number of cigarettes that are smoked per day
13	BY MS. PARFITT:	13	in the home, and with a very elaborate procedure
14	Q Okay. You've worked an secondhand smoke	14	of asking not only the person who is answering the
15	studies, correct?	15	questionnaire but about all the other people that
16	A Yes.	16	are in and out of the house that day, so we get a
17	Q How do you determine the dose for those?	17	count of cigarettes.
18	MS. BROWN: Objection to the form.	18	We also use different types of
19	THE WITNESS: So the dose of secondhand	19	particulate matter monitors, and we've established
20	smoke?	20	that you can estimate about 1 microgram per meter
21	BY MS. PARFITT:	21	cubed of particulate matter per cigarette smoked
22	Q Mm-hmm.	22	in the home. So we've got an estimate that way.
23	A So it depends, right. So at the moment,	23	We we collect nicotine and cotinine
24	it so it depends upon which kind of study. And	24	from a variety of sources, so we've collected
25	when you say "you," do you mean you in the broad	25	hair, saliva, urine, and blood. And so depending
	Page 403		Page 405
1	sense or me, Greg Diette?	1	upon which study and which population, we can
0			
2	Q Well, Greg Diette has been doing	2	estimate something about dose based on what
3	research on secondhand smoke, and you, Greg		estimate something about dose based on what their what their sort of biomarker is.
	research on secondhand smoke, and you, Greg Diette, has indicated that dose is important to	2	estimate something about dose based on what their what their sort of biomarker is. Q All right. How much have you
3	research on secondhand smoke, and you, Greg Diette, has indicated that dose is important to you. So what I'd like to know is how you measure	2 3	estimate something about dose based on what their what their sort of biomarker is.  Q All right. How much have you understanding those metrics, for lack of a better
3 4	research on secondhand smoke, and you, Greg Diette, has indicated that dose is important to you. So what I'd like to know is how you measure the dose in your secondhand smoke.	2 3 4	estimate something about dose based on what their what their sort of biomarker is. Q All right. How much have you
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Gregory B. Diette, M.D.

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1	inhaled it enough in order to get that particular	1	couple-year study and, you know, tens of thousands
2	fluid level high enough to for you to measure	2	of dollars spent doing it?
3	it. And same with saliva and same with hair.	3	MR. LOCKE: Objection.
4	BY MS. PARFITT:	4	MS. BROWN: Objection to the form.
5	Q Okay.	5	There are multiple questions in there, Counsel.
6	A I left one out too. We also measure	6	Can you rephrase?
7	airborne nicotine, and so that's another	7	BY MS. PARFITT:
8	indicator. So I was talking about cotinine that's	8	Q Do you understand the question?
9	measured in in the people, but we also have	9	A The the last part you said I'll
10	nicotine matches, and we'll measure nicotine	10	try to paraphrase it so we know we're talking
11	directly in the environment.	11	about the same thing. I have not I have not
12	Q Based upon I meant to ask this	12	done anything to inform the medical community
13	earlier. Based upon your study of ovarian cancer	13	about the findings so far from my you know,
14	and talcum powder products that you've done for	14	from my work on these cases.
15	Johnson & Johnson, have you made any of these	15	Q Do you intend to do so?
16	recommendations to Johnson & Johnson as to how	16	A I don't have any active intention to do
17	what kind of study they could perform in order to	17	it right now.
18	ascertain dose?	18	Q Okay. Do you intend to have your report
19	MS. BROWN: What?	19	peer published?
20	MR. LOCKE: Objection.	20	A It's not in the right format for that.
21	MS. BROWN: Objection to the form of the	21	Q Okay. Do you intend to do any
22	question.	22	meta-analysis of your work?
23	BY MS. PARFITT:	23	MS. BROWN: Objection to the form.
24	Q Let me ask it again.	24	THE WITNESS: Not on that not on that
25	A Oh, no, I heard it. I was just I	25	topic.
	Page 407		Page 409
1	guess the broad answer is no. I mean I haven't	1	BY MS. PARFITT:
2	made any recommendations about studies to Johnson	2	Q Okay. And if you saw with regard to
3	& Johnson for for anything.	3	Health Canada, they have given they gave
4	Q Okay. And the reason I ask is, your	4	individuals an opportunity to comment on the work
5	work appears to be reviewing and surveying the	5	that they did and present that to them.
6	literature for Johnson & Johnson in order to give	l .	
		6	You saw that, correct?
7	_	6 7	You saw that, correct?  A Yes.
	litigation opinions on whether or not talcum	7	A Yes.
7 8 9	_		
8	litigation opinions on whether or not talcum powder products can cause ovarian cancer.	7 8	<ul><li>A Yes.</li><li>Q Okay. So you had an opportunity as</li></ul>
8 9	litigation opinions on whether or not talcum powder products can cause ovarian cancer.  MR. LOCKE: Objection.	7 8 9	A Yes. Q Okay. So you had an opportunity as someone who's reviewed the literature to write to Health Canada and inform them of your concern
8 9 10	litigation opinions on whether or not talcum powder products can cause ovarian cancer.  MR. LOCKE: Objection.  MS. BROWN: Objection to the form of the	7 8 9 10	A Yes. Q Okay. So you had an opportunity as someone who's reviewed the literature to write to Health Canada and inform them of your concern about the manner in which they conducted their
8 9 10 11	litigation opinions on whether or not talcum powder products can cause ovarian cancer.  MR. LOCKE: Objection.  MS. BROWN: Objection to the form of the question.	7 8 9 10 11	A Yes. Q Okay. So you had an opportunity as someone who's reviewed the literature to write to Health Canada and inform them of your concern about the manner in which they conducted their study. Fair?
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103 (Pages 406 to 409)

	Page 410		Page 412
1	Q Something opportunist came up. Is that	1	MS. BROWN: Objection.
2	the fact that you are being engaged in this	2	THE WITNESS: The only studies I've seen
3	litigation	3	are the ones that I think that were cited by
4	A No.	4	by IARC with if that's what we're talking
5	MS. BROWN: Objection	5	about, is like women who were about to have
6	BY MS. PARFITT:	6	surgery for some other reason and and different
7	Q as an expert witness?	7	things placed either in their uterus or vagina,
8	MS. BROWN: Objection to the form.	8	although not necessarily talc. I mean all kinds
9	THE WITNESS: Oh, no, I just see I	9	of things, you know, carbon particles,
10	think the reason that I have it in front of me is	10	radiolabeled particles, different things that
11	because it it seemed to help help	11	aren't talc.
12	plaintiffs' experts to be able to say something	12	(Counsel conferring.)
13	else about this this story. And if if it	13	BY MS. PARFITT:
14	had said something else, then I probably wouldn't	14	Q So sitting here today, is it your
15	even have heard about it.	15	testimony that you have not reviewed or seen in
16	BY MS. PARFITT:	16	the medical literature that particles of talc can
17	Q Okay. This story, Dr. Diette, is about	17	migrate to the ovaries, lymph nodes, of a woman's
18	women who are dying of ovarian cancer	18	body?
19	MS. BROWN: Careful what's the	19	MS. BROWN: Objection to the form of the
20	question?	20	question.
21	BY MS. PARFITT:	21	MR. LOCKE: Objection.
22	Q having been exposed to talcum powder	22	THE WITNESS: So so the study would
23	products.	23	be one where somebody applied talc to the perineum
24	Do you understand that?	24	and then demonstrated that it migrated from there
25	MR. LOCKE: Objection.	25	to the ovaries or into some lymph node somewhere?
1	Page 411		Page 413
1	MS. BROWN: Objection to the form of the	1	BY MS. PARFITT:
2	MS. BROWN: Objection to the form of the question.	2	BY MS. PARFITT: Q That's right.
2	MS. BROWN: Objection to the form of the question.  THE WITNESS: I understand the general	2	BY MS. PARFITT: Q That's right. A I have not seen that study.
2 3 4	MS. BROWN: Objection to the form of the question.  THE WITNESS: I understand the general notion is about ovarian cancer and whether there	2 3 4	BY MS. PARFITT:  Q That's right.  A I have not seen that study.  Q Okay. You've read the Schildkraut
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	Page 414		Page 416
1	this?	1	MR. LOCKE: Objection.
2	MS. PARFITT: Sure. What number are we	2	BY MS. PARFITT:
3	up to?	3	Q Okay. Do you agree that there is
4	MS. BROWN: Oh, 29. I'm sorry. It's	4	reliable scientific literature in the
5	there. My bad.	5	peer-reviewed studies to support that it is
6	BY MS. PARFITT:	6	biologically plausible for talc products to
7	Q Do you have that in front of you,	7	migrate from the vagina to the ovaries following
8	Doctor?	8	perineal application?
9	A I do.	9	A I'm not aware of that study that has
10	Q Okay. And if I can direct your	10	shown that.
11	attention to pages 14, 16.	11	Q Have you seen the Penninkilampi study?
12	A Got you.	12	A Oh.
13	Q Do you have that?	13	MS. BROWN: Objection.
14	Do you see where the authors state:	14	THE WITNESS: Yes, I have.
15	"Lung inhalation of powder could be a biologically	15	BY MS. PARFITT:
16	plausible mechanism for the association between	16	Q Okay. Why don't we take a look at that.
17	nongenital powder use and increased EOC risk,	17	Let's pull it up, and we'll make it
18	particularly non-serous EOC."	18	Exhibit No. 30.
19	Do you see that?	19	(Diette Exhibit No. 30 was marked
20	A I do. It's the top of the first column	20	for identification.)
21	in the the rest of the incomplete paragraph.	21	BY MS. PARFITT:
22	Q Okay. Do you see that?	22	Q Right here. And if I may, Doctor, let
23	A I do.	23	me direct your attention to the discussion section
24	Q Okay. Do you agree with that?	24	of Penninkilampi on page 45.
25	MR. LOCKE: Objection.	25	A Page 45?
			Page 417
1	THE WITNESS: Only wall no Only in	1 1	
1	THE WITNESS: Only well, no. Only in	1	Q 45.
2	the broadest sense that lots of things could be,	2	Q 45. A Yep.
2 3	the broadest sense that lots of things could be, but not because there's any evidence to show that	2 3	<ul><li>Q 45.</li><li>A Yep.</li><li>Q Do you have that?</li></ul>
2 3 4	the broadest sense that lots of things could be, but not because there's any evidence to show that inhalation of powder is a way to get to the	2 3 4	<ul><li>Q 45.</li><li>A Yep.</li><li>Q Do you have that?</li><li>A I'm there, yep.</li></ul>
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	Page 418		Page 420
1	THE WITNESS: So so I agree with a	1	inflammatory hypothesis, as repeated exposure
2	lot of this, right. So I agree that the mechanism	2	would induce a longer period of chronic
3	is uncertain. Right. I agree that it has been	3	inflammation, and therefore should increase the
4	previously proposed 20 years ago by the citation	4	predisposition to the development of ovarian
5	that they have that that may ascend from the	5	cancer."
6	vagina, and instigate a chronic inflammation	6	Did I read that correctly?
7	response.	7	A You did.
8	They don't cite anything more modern	8	Q All right. Do you agree with that
9	than that one from 20 years ago, though. And	9	statement, that chronic inflammation as a
10	where it talks about it may be mutagenic and	10	biologically plausible hypothesis could induce
11	promote carcinogenesis	11	carcinogenicity?
12	BY MS. PARFITT:	12	MR. LOCKE: Objection.
13	Q Correct.	13	MS. BROWN: Counsel, are you
14	A I don't I don't think that's well	14	intentionally not reading the rest of that
15	supported either.	15	paragraph?
16	Q Is migration of tale a biologically	16	MS. PARFITT: No, I I'm getting
17	plausible mechanism by which talc can reach the	17	there.
18	ovaries?	18	MS. BROWN: Okay.
19	MS. BROWN: Objection to the form.	19	MS. PARFITT: Yeah.
20	MR. LOCKE: Objection.	20	THE WITNESS: Well, I disagree with the
21	THE WITNESS: If it were true, it could	21	fact that the small difference between 3600, plus
22	be supportive of that. But I don't see any any	22	or minus, lifetime applications supports a an
23	evidence that it's true.	23	inflammatory theory, because that's got nothing
24	BY MS. PARFITT:	24	too do with inflammation. It's really just a a
25	Q Is biological plausibility essential for	25	total number of applications.
	Page 419		Page 421
1	causality?	1	BY MS. PARFITT:
0	•	l .	
2	A No, it's it's one important criterion	2	Q Perhaps I can simplify my answer. Do
3	to consider.	l .	Q Perhaps I can simplify my answer. Do you have an opinion as to whether or not chronic
	to consider.  Q Does biological plausibility mean it	2	Q Perhaps I can simplify my answer. Do you have an opinion as to whether or not chronic inflammation can be a biologically plausible
3	to consider.  Q Does biological plausibility mean it must be proved?	2	Q Perhaps I can simplify my answer. Do you have an opinion as to whether or not chronic inflammation can be a biologically plausible method for promoting carcinogenesis?
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3 4 5 6	to consider.  Q Does biological plausibility mean it must be proved?  MS. BROWN: Objection.	2 3 4 5 6	Q Perhaps I can simplify my answer. Do you have an opinion as to whether or not chronic inflammation can be a biologically plausible method for promoting carcinogenesis?  MS. BROWN: Objection to the form.  THE WITNESS: In in all kinds of cancer or ovarian cancer?
3 4 5 6 7	to consider.  Q Does biological plausibility mean it must be proved?  MS. BROWN: Objection.  THE WITNESS: And I assume we're talking	2 3 4 5 6 7	Q Perhaps I can simplify my answer. Do you have an opinion as to whether or not chronic inflammation can be a biologically plausible method for promoting carcinogenesis?  MS. BROWN: Objection to the form.  THE WITNESS: In in all kinds of
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1	Page 422		Page 424
	cells, like these precursor cells, and and at	1	BY MS. PARFITT:
2	least, you know, from histologic specimens, not	2	Q T-A-H-E-R.
3	seeing evidence of inflammation. And I haven't	3	A Oh.
4	really seen much that that would confirm that	4	Q 2018.
5	there's a link between chronic inflammation.	5	A Sorry, I was saying Taher.
6	BY MS. PARFITT:	6	Q No, no problem.
7	Q What I'm asking you is, based upon your	7	A But I don't now how you
8	review, Dr. Diette, have you seen anything in the	8	Q You could be right on that. Probably
9	peer-reviewed literature that there are	9	are.
10	biologically plausible mechanisms of tale's	10	A I don't know.
11	carcinogenicity demonstrated by chronic	11	I did.
12	inflammation from migration of the talc to the	12	Q Do you see where Taher authors found
13	ovaries?	13	that there was biologically plausible evidence of
14	MS. BROWN: Objection. I don't	14	inflammation from talc exposure?
15	understand that question.	15	MS. BROWN: Objection. Counsel, can we
16	MR. LOCKE: Objection.	16	see the article if you want to ask him about it?
17	THE WITNESS: Would you	17	MR. LOCKE: Objection.
18	BY MS. PARFITT:	18	BY MS. PARFITT:
19	Q The question let me rephrase it.	19	Q You've read the article. Do you know
20	A Okay.	20	the answer to that?
21	Q Is there are there studies in the	21	MS. BROWN: But it's not a memory test.
22	peer-reviewed literature that support an	22	MS. PARFITT: No, it's not, but perhaps
23	association of inflammation and increased risk of	23	he can answer. I didn't ask you the question.
24	ovarian cancer?	24	BY MS. PARFITT:
25	MS. BROWN: Objection to the form, asked	25	Q Do you know the answer to that?
	Page 423		Page 425
1	and answered.	1	A Well, the paper wasn't about that, so I
2	BY MS. PARFITT:	2	don't I don't remember whether there was sort
3	Q Is there something in the literature?	3	of a preamble thing, but they they weren't
4	MS. BROWN: Objection.	4	really analyzing that. They were doing a
5	BY MS. PARFITT:	5	meta-analysis, you know, sort of combining the epi
6	Q Not whether there is a lot or a little.	6	studies. So, I mean, I don't remember what their
7	Is there anything in the peer-reviewed literature	7	statement was, but when you
8	that you've seen that supports an association	8	Q All right. Did you
9	between inflammation and an increased risk of	9	A I'm sorry, I just want to say, but if
10	ovarian cancer?	10	you say that they found it, by finding it, I don't
11	MS. BROWN: Objection to the form.	11	think they demonstrated it or it was a finding
12	THE WITNESS: I've seen the paper where	12	from their study per se.
13	C-reactive protein in the serum popped out of	13	Q Okay. Have you read Langseth, 2008?
14	dozens of different markers of inflammation and	14	A Langseth, 2008?
15	predated the diagnosis of ovarian cancer.	15	Q Correct.
16	I guess I haven't really seen something	16	A Is that a meta-analysis?
17	that shows that chronic inflammation in the	17	Q Correct.
18	ovaries is is a precursor to ovarian cancer or	18	A Yes.
19	that talc induces that particular chronic	19	Q All right. And do you see where the
20	inflammation that would in turn lead to cancer.	20	Langseth authors also found migration and and
1 0-	BY MS. PARFITT:	21	concluded that there was chronic inflammation that
21	Q Have you read Taher? You've read the	22	was biologically plausible?
21 22			
	Taher study, correct?	23	MS. BROWN: No, I I object. If
22		23 24	MS. BROWN: No, I I object. If you're going to quote articles

	Page 426		Page 428
1	Q Do you remember?	1	He doesn't have the article.
2	MS. BROWN: I would request the	2	MS. PARFITT: That's fine.
3	article.	3	MS. BROWN: And he's never read it.
4	MS. PARFITT: I can do that.	4	BY MS. PARFITT:
5	BY MS. PARFITT:	5	Q Look at the abstract, first sentence.
6	Q Do you know, Doctor?	6	It says: "Perineal talc use is associated with
7	A I don't remember what they said.	7	ovarian carcinoma in many case-control studies.
8	(Counsel conferring.)	8	Such talc may migrate to pelvic organs and
9	MS. PARFITT: Doctor, if we can take a	9	regional lymph nodes, with both clinical and legal
10	quick break here	10	significance."
11	THE WITNESS: Sure.	11	Did I read that correctly?
12	MS. PARFITT: right now, so maybe I	12	A Yes.
13	can	13	Q All right. Would it be I believe you
14	THE WITNESS: Yeah, it's a good time.	14	had some concerns about the Heller study that we
15	MS. PARFITT: shorten things.	15	talked about earlier because it involved some
16	THE VIDEOGRAPHER: The time is 4:59 p.m.	16	unexposed what you testified were unexposed
17	We're going off the record.	17	women.
18	(Recess.)	18	MS. BROWN: Objection to the form.
19	THE VIDEOGRAPHER: The time is 5:12 p.m.	19	THE WITNESS: Correct, women who
20	and we're back on the record.	20	reported not being perineal talc users.
21	MS. PARFITT: I apologize.	21	BY MS. PARFITT:
22	BY MS. PARFITT:	22	Q Right. Okay. You understand in this
23	Q Dr. Diette, and I apologize, I have only	23	study that what Drs. McDonald and Godleski were
24	one copy that isn't marked up, so we're going to	24	doing were looking at particles in exposed women.
25	have to put this and substitute it on the on	25	MS. BROWN: No, he doesn't understand
	Page 427		Page 429
1	the ELMO, if I may. We've done pretty good with	1	that because he doesn't have the study and he
2	copies all day today.	2	hasn't read it. I object. It's not fair.
3	So here we go.	3	THE WITNESS: I honestly have no idea
4	MR. ROSEN: This will be Exhibit 31.	4	what they've done.
5	(Diette Exhibit No. 31 was marked	1 -	
6	£: .1	5	BY MS. PARFITT:
	for identification.)	6	Q Okay. Well, do you dispute that talc
7	BY MS. PARFITT:		Q Okay. Well, do you dispute that talc particles can migrate to the pelvic organs and
7 8	BY MS. PARFITT:  Q All right. Dr. Diette, this is an	6	Q Okay. Well, do you dispute that talc
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	Page 430		Page 432
1	MS. BROWN: Of course.	1	You had testified earlier that you
2	BY MS. PARFITT:	2	disagree with Health Canada when they state that
3	Q If it's from the vaginal area to the	3	talc can migrate to the ovaries; is that correct?
4	ovaries and the lymph nodes, does that make a	4	MR. LOCKE: Objection.
5	difference whether	5	MS. BROWN: Objection. Misstates prior
6	MR. LOCKE: Objection.	6	testimony. I don't even think he said that.
7	MS. BROWN: Objection to the form, lacks	7	BY MS. PARFITT:
8	foundation, calls for speculation about a document	8	Q Well, let me ask you. In the Health
9	he told you he's never read.	9	Canada report, they discuss the fact that it is
10	MR. LOCKE: Does the witness have a	10	biologically plausible for talc to migrate to the
11	copy?	11	ovaries and then cause an inflammatory process.
12	MS. BROWN: No. That's the objection.	12	Do you agree or disagree with that?
13	MS. PARFITT: Tom, we didn't we only	13	MR. LOCKE: Objection.
14	have one copy of it.	14	MS. BROWN: Objection. Lacks
15	MR. LOCKE: I think you need to disclose	15	foundation. Do you want to show him where they
16	to the witness that three of these authors are	16	said that?
17	paid experts, et cetera	17	THE WITNESS: I don't remember their
18	MS. PARFITT: Tom, Tom, Tom, Tom.	18	statement about that.
19	MR. LOCKE: Come on.	19	BY MS. PARFITT:
20	MS. BROWN: No, but to be fair, you	20	Q You don't. Okay.
21	guys, if you want to ask him questions, he's got	21	How about this statement. Go down to
22	to look at it. I'm going to take it off the ELMO	22	I believe it's one, two, three the third
23	and give it to him if you're going to continue	23	paragraph. Do you see that? It starts with
24	asking him questions.	24	"While."
25	BY MS. PARFITT:	25	A No.
	Page 431		Page 433
1	Q I'm not going to ask him any more	1	Q No?
2	questions on it, Doctor.	2	A Oh, I'm on a different page.
3	A Okay. Thank you.	3	Q I'm sorry. Page 5. Page 5.
4	Q All right. Let me show you	4	A Okay.
5	MR. LOCKE: Come on. Give him if	5	Q Okay. "While there exists no direct
6	you're going to give him if you're going to ask	6	proof of talc and ovarian carcinogenesis, the
7	him about it	7	potential for particles to migrate from the
8	MR. TISI: You're not even on record.	8	perineum into the vagina to the peritoneal cavity
9	MS. PARFITT: Tom, it was just	9	is indisputable."
10	MS. BROWN: Hey, hey, hey, guys. It's	10	Do you see that?
11	the end of the day.	11	A I do.
12	MS. PARFITT: Okay. Let's don't	12	Q Okay. Do you agree with the FDA?
13	MS. BROWN: Let's get through this.	13	MS. BROWN: Objection to the form.
14	(Diette Exhibit No. 32 was marked	14	THE WITNESS: So there's no citation for
15	for identification.)	15	that. I don't know how they get I mean I don't
16	BY MS. PARFITT:	16	know why they make that statement, and I it
17	Q 32. Let me show you what's been marked	17	certainly doesn't seem to be indisputable, because
18	as Plaintiffs' Exhibit 32.	18	there several of the articles that we've looked
	I need a copy. There you go. Sorry.	19	at today and others say it's not clear what the
19			mechanism is or the biologic plausibility. So
19 20	A Thank you.	20	
19 20 21	<ul><li>A Thank you.</li><li>Q Okay. You previously testified that you</li></ul>	21	it's it's obviously disputable, at the very
19 20 21 22	A Thank you.  Q Okay. You previously testified that you take a look at it. You read this before, the	21 22	it's it's obviously disputable, at the very least, but there's no citation, so it's hard to
19 20 21 22 23	A Thank you. Q Okay. You previously testified that you take a look at it. You read this before, the FDA letter 2014?	21 22 23	it's it's obviously disputable, at the very least, but there's no citation, so it's hard to know how to how to process this.
19 20 21 22	A Thank you.  Q Okay. You previously testified that you take a look at it. You read this before, the	21 22	it's it's obviously disputable, at the very least, but there's no citation, so it's hard to

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	Page 434		Page 436
1	regard to whether or not talc can migrate, do you	1	think my answer was along the lines of I haven't
2	dispute that?	2	seen a study that shows that that's true.
3	MS. BROWN: Objection. Misstates the	3	BY MS. PARFITT:
4	document.	4	Q We talked about Schildkraut. We talked
5	THE WITNESS: I don't I don't dispute	5	about Schildkraut, didn't we?
6	that they said it obviously, because it's right	6	A Yeah, they didn't show that either,
7	here, but there's just no citation for it, and	7	though.
8	there's no information that tells who in	8	Q When you say they didn't show it, have
9	particular thinks that.	9	they opined in medical or let me ask you this
10	BY MS. PARFITT:	10	question. I see the disconnect.
11	Q Well, the Food and Drug Administration	11	Is there evidence contained in
12	is our regulatory body here in the United States,	12	peer-reviewed scientific articles wherein it is
13	correct?	13	stated that talcum powder products can migrate to
14	A It is one.	14	the ovaries?
15	MR. LOCKE: Objection.	15	MS. BROWN: Objection.
16	BY MS. PARFITT:	16	MR. LOCKE: Objection.
17	Q All right. Would you agree that	17	MS. BROWN: Misstates everything we've
18	dissemination of information that is accurate and	18	looked at and his testimony.
19	truthful is is something that they would	19	THE WITNESS: I think there's been
20	probably take quite seriously? Would you agree?	20	opinions of different people in different articles
21	MS. BROWN: Objection.	21	that are both supportive and not supportive of
22	THE WITNESS: I I hope so.	22	that statement.
23	BY MS. PARFITT:	23	BY MS. PARFITT:
24	Q Right. And would you agree that the FDA	24	Q All right. So you've seen scientific
25	would not be disseminating information about the	25	
25	would not be disseminating information about the	⊿5	writers who have said talc can migrate to the
	would not be disseminating information about the	25	
	Page 435	25	Page 437
1	Page 435 potential for particulates to migrate from the	1	Page 437 ovaries, and you've seen scientific articles that
1 2	Page 435 potential for particulates to migrate from the perineum, the vagina to the peritoneal cavity, and		Page 437 ovaries, and you've seen scientific articles that say that's more questionable. Is that fair?
1 2 3	Page 435  potential for particulates to migrate from the perineum, the vagina to the peritoneal cavity, and say it's indisputable if they didn't have some	1	Page 437 ovaries, and you've seen scientific articles that say that's more questionable. Is that fair? MS. BROWN: Objection. Not fair.
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	Page 438		Page 440
1	Q So I'm going to share this with you,	1	Take a moment and take a look at that, to eyeball
2	and actually, if we could put it on the ELMO,	2	that.
3	and then I will give it to you so I can at least	3	MS. BROWN: Take as long as you need to
4	identify it for counsel.	4	inform your response
5	Is that fair?	5	MS. PARFITT: It's a one-page document.
6	A Yeah. We will see how it goes.	6	MR. LOCKE: No. This this is a
7	Q All right. Let me show you it is	7	document that he hasn't seen before.
8	marked September 30th, 2004, and I will represent	8	MS. PARFITT: That's correct.
9	that it is to Bill Ashton from Richard Zazenski,	9	MR. LOCKE: Why don't we go off the
10	and it's a Luzenac document.	10	record.
11	MS. BROWN: What? I'm going to object	11	MS. PARFITT: It's one page, Doctor.
12	on form and foundation.	12	MS. BROWN: Right, and that's just fair.
13	BY MS. PARFITT:	13	MS. MILLER: If you're going to ask him
14	Q Okay. Can you see that, Doctor? I	14	questions about what you just threw out there
15	don't want to strain your eyes too much.	15	MS. BROWN: That's fine. That's fine,
16	MS. BROWN: No, we need to give him	16	but you understand there's no foundation. He's
17	he's never seen it. He hasn't reviewed it. His	17	never relied it.
18	opinions are not based on it. If you want to ask	18	MS. PARFITT: Okay, guys
19	him questions about it, he needs to hold it and	19	MS. BROWN: So if we want to ask
20	look at it.	20	questions
21	BY MS. PARFITT:	21	THE REPORTER: Excuse me.
22	Q I'm going to give it to you. I'm going	22	MS. PARFITT: I'm not having him
23	to let you hold it in one moment.	23	whoa, whoa.
24	Dr. Diette, this is a document I will	24	(A discussion was held off the record.)
25	represent that's dated September 30, 2004, and	25	BY MS. PARFITT:
	Page 439		Page 441
1	that would have preceded any litigation.	1	Q Dr. Diette, I'm simply referring to the
2	And it states: "Bill, I came across	2	cover letter.
3	this paper this morning published in the April	3	A Oh.
4	2004 journal Human Reproduction, an official	1 4	
	200 i Journal Haman Reproduction, un official	4	Q And that's all, just one page. Do you
5	journal of the European Society for Human	5	Q And that's all, just one page. Do you see that?
5 6			
	journal of the European Society for Human	5	see that?
6	journal of the European Society for Human Reproduction and Embryology. It offers some	5 6	see that? A I do.
6 7	journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence in support of the migration	5 6 7	see that?  A I do. Q Okay. And that's what I just read into
6 7 8	journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence in support of the migration hypothesis. Combine this evidence with the theory	5 6 7 8	see that?  A I do. Q Okay. And that's what I just read into the record. Do you see that?
6 7 8 9	journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence in support of the migration hypothesis. Combine this evidence with the theory that the talc deposition on the ovarian epithelium	5 6 7 8 9	see that?  A I do. Q Okay. And that's what I just read into the record. Do you see that? A I do.
6 7 8 9 10	journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence in support of the migration hypothesis. Combine this evidence with the theory that the talc deposition on the ovarian epithelium initiates epithelium inflammation, which leads to	5 6 7 8 9	see that?  A I do. Q Okay. And that's what I just read into the record. Do you see that? A I do. Q Okay. And do you see back in 2004,
6 7 8 9 10 11	journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence in support of the migration hypothesis. Combine this evidence with the theory that the talc deposition on the ovarian epithelium initiates epithelium inflammation, which leads to epithelium carcinogenesis, and you have a	5 6 7 8 9 10	see that?  A I do. Q Okay. And that's what I just read into the record. Do you see that? A I do. Q Okay. And do you see back in 2004, there was information with regard and I have to
6 7 8 9 10 11 12	journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence in support of the migration hypothesis. Combine this evidence with the theory that the talc deposition on the ovarian epithelium initiates epithelium inflammation, which leads to epithelium carcinogenesis, and you have a potential formula for NTP classifying talc as a	5 6 7 8 9 10 11 12	see that?  A I do. Q Okay. And that's what I just read into the record. Do you see that? A I do. Q Okay. And do you see back in 2004, there was information with regard and I have to see it, I can't be sorry. I can't memorize it
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Page 444		Page 442	
his an e-mail or a fax? It	1 it that th	MS. BROWN: Objection to the speech,	1
m Ness's paper or Ness's paper	2 has someth	lacks foundation. I also believe that's an Imerys	2
m this	3 has someth	document.	3
Γ:	4 BY MS. P.	THE WITNESS: So a few things, right.	4
e something from Ness's paper,	5 Q Th	So one is I I've never seen that, so I don't	5
	6 correct.	even know what it is. I don't know who those	6
VN: Well, objection.	7 MS.	people are. That I don't know what their	7
NESS: But this is		qualifications are to consider something to be	8
VN: Don't don't speculate.	9 MS.	compelling evidence or if that's the word that was	9
	10 No one wa	used.	10
ITT: So we won't talk about		BY MS. PARFITT:	11
VN: Just wait for a question,	12 MS.	Q Mm-hmm.	12
	13 and we'll d	A I have not seen the article that's	13
Γ:	14 BY MS. P.	attached to the back of it.	14
you see on the first page of		Q Okay.	15
in the left-hand column		A But it's hard to say much about that.	16
n, where Dr. Ness states:		Q Yes.	17
tails cell damage, oxidative		Let me show you what we will have marked	18
ons of cytokines and		as Exhibit 34, and I'll represent to you it's an	19
of which may be mutagenic.		article by Roberta Ness, "Possible Role of Ovarian	20
at inflammation is a		Epithelial Inflammation."	21
al contributor to the development		(Diette Exhibit No. 34 was marked	22
suggests a directed approach to		for identification.)	23
suggests a directed approach to	24 future rese	BY MS. PARFITT:	24
that?		Q Have you seen this article before?	25
Page 445		Page 443	
Page 445	1 AId	Page 443 A I have.	1
Page 445 by you agree with that statement?			1 2
	2 Q O	A I have.	
o you agree with that statement?	2 Q Ol 3 MR	A I have. Q Okay. Do you see on page 2	2
o you agree with that statement? KE: Objection.	2 Q Ol 3 MR 4 MS	A I have.  Q Okay. Do you see on page 2 MS. PARFITT: Where is the other one?	2
o you agree with that statement? KE: Objection. WN: Objection to the form.	2 Q OF 3 MR 4 MS 5 TH	A I have.  Q Okay. Do you see on page 2 MS. PARFITT: Where is the other one? (Counsel conferring.)  BY MS. PARFITT:	2 3 4
o you agree with that statement? KE: Objection. WN: Objection to the form. NESS: So, I haven't read this	<ul> <li>Q Ol</li> <li>3 MR</li> <li>4 MS</li> <li>5 TH</li> <li>6 article in a</li> </ul>	A I have.  Q Okay. Do you see on page 2 MS. PARFITT: Where is the other one? (Counsel conferring.)	2 3 4 5
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o you agree with that statement? KE: Objection. WN: Objection to the form. NESS: So, I haven't read this It is from about 20 years	2 Q Old 3 MR 4 MS 5 TH 6 article in a 7 ago. And 8 a reasonab	A I have.  Q Okay. Do you see on page 2 MS. PARFITT: Where is the other one? (Counsel conferring.)  BY MS. PARFITT: Q If I could you have in front of you the Zazenski thank you.	2 3 4 5 6 7
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	Page 446		Page 448
1	one does not need to prove mechanism in order to	1	exposure can lead to the outcome that you're
2	find causality, correct?	2	interested in.
3	A I need to prove	3	BY MS. PARFITT:
4	MR. LOCKE: Objection.	4	Q Okay. Doctor, from your review of the
5	MS. BROWN: Objection to form.	5	peer-reviewed scientific literature, have you read
6	THE WITNESS: Sorry. Wow, sorry.	6	where study authors who have actually looked at
7	BY MS. PARFITT:	7	the issue of migration and other biological
8	Q We had a chorus.	8	plausible methods by which talc can get to the
9	A Yeah.	9	ovary?
10	No, you don't need to prove it, but	10	A I guess
11	it's	11	MS. BROWN: I object. I don't
12	Q You don't need to prove mechanism.	12	understand.
13	A You don't need to prove mechanism in	13	THE WITNESS: I mean I've looked at both
14	order to establish causation, but it's hard to get	14	the human and the animal studies that I could find
15	there for a low observed risk if you don't have	15	cited on the topic. And and you said that
16	biological plausibility.	16	talc talc can get to the ovary?
17	Q I'll take that back yes, I'm sorry.	17	BY MS. PARFITT:
18	I hope I didn't ask you this before, but	18	O Mm-hmm.
19	is biological plausibility the same as proof of	19	A Because, you know, some are not talc,
20	mechanism?	20	right. There there are other kinds of
21	MR. LOCKE: Objection.	21	particles or substances. And so I've looked at
22	MS. BROWN: Objection to the form of the	22	both the animal and the human studies that I could
23	question.	23	find.
24	THE WITNESS: Proof of I don't know	24	Q And in those studies that you have
25	if I would use the so "proof of mechanism"	25	reviewed, have you seen where those authors who
	Page 447		Page 449
1	sounds like a term in a way, but maybe not one	1	have studied the issue of biological plausibility
1 2	sounds like a term in a way, but maybe not one that's in my vocabulary. Like people talk about	1 2	have studied the issue of biological plausibility and mechanisms by which talc can get to the ovary
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2	sounds like a term in a way, but maybe not one that's in my vocabulary. Like people talk about proof of concept just as a study design, which I don't know if that's the same thing, but I	2	have studied the issue of biological plausibility and mechanisms by which talc can get to the ovary
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2 3 4	sounds like a term in a way, but maybe not one that's in my vocabulary. Like people talk about proof of concept just as a study design, which I don't know if that's the same thing, but I	2 3 4	have studied the issue of biological plausibility and mechanisms by which talc can get to the ovary have concluded in their articles that that is indeed a pathway?
2 3 4 5	sounds like a term in a way, but maybe not one that's in my vocabulary. Like people talk about proof of concept just as a study design, which I don't know if that's the same thing, but I don't I don't I don't know "proof of	2 3 4 5	have studied the issue of biological plausibility and mechanisms by which talc can get to the ovary have concluded in their articles that that is indeed a pathway?  MS. BROWN: Objection.  MR. LOCKE: Objection.
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Gregory B. Diette, M.D.

	Page 450		Page 452
1	took that as kind of mixed evidence that even in	1	MS. BROWN: Objection to the form.
2	animals, assuming that there is an appropriate	2	MR. LOCKE: Objection.
3	animal model, that they're not getting the same	3	THE WITNESS: So I I looked for
4	answer based on which animal it is.	4	all the things that we talked about I don't
5	BY MS. PARFITT:	5	know which ones we're talking about now in terms
6	Q Does exposure of a disease have to be	6	of the epidemiology studies.
7	proven in order to have a biologically plausible	7	BY MS. PARFITT:
8	mechanism?	8	Q Correct.
9	MS. BROWN: Objection to the form.	9	A So I've seen some that do and some that
10	MR. LOCKE: Objection.	10	don't propose that. Some I think are and I'm
11	THE WITNESS: So I don't know if I	11	paraphrasing but are sort of more along the
12	understand that. So are you saying that so say	12	lines of we just don't know or there's a lot more
13	it again. I'm sorry.	13	work needed, and and things of that sort.
14	BY MS. PARFITT:	14	Q Are there a lot on the lines of
15	Q Sure. It was probably a bad question.	15	migration of talc excuse me.
16	MS. BROWN: The realtime	16	Are there a lot of articles that you've
17	BY MS. PARFITT:	17	reviewed where they have authors have stated
18	Q Does one need does a scientist need	18	that talc can migrate to the ovaries?
19	to know the precise mechanism in order to	19	A I wouldn't say
20	determine whether or not it's biologically	20	MS. BROWN: Objection.
21	plausible for some toxin to cause some disease?	21	THE WITNESS: I wouldn't say a lot. And
22	MS. BROWN: Objection to the form.	22	I haven't seen anything as strong as that FDA
23	MR. LOCKE: Objection.	23	statement, you know, I mean, where where
24	THE WITNESS: So "precise" might be a	24	there's some, you know, certainty that is coupled
25	a term that matters, but but it can be a work	25	with that kind of a statement.
	Page 451		Page 453
1	in progress in the sense that you can have some	1	BY MS. PARFITT:
2	information or no information or lots of	2	Q But you've certainly seen where the
3	information. So there can be, you know, quite a	3	authors have opined and discussed biologically
4	spectrum of information you would have about the	4	plausible mechanism by mechanisms by which
5	plausibility.	5	talcum powder products can cause ovarian cancer.
6	BY MS. PARFITT:	6	MR. LOCKE: Objection.
7	Q I think what I'm asking is, does the	7	MS. BROWN: Objection. Continues to
8	mechanism of disease need to be proven in order to	8	
^		0	misstate his testimony.
9	find causality?	9	misstate his testimony.  THE WITNESS: What's what's different
9 10		"	
	find causality?	9	THE WITNESS: What's what's different
10	find causality?  MS. BROWN: Objection to the form.	9	THE WITNESS: What's what's different about that than what I already answered?
10 11	find causality?  MS. BROWN: Objection to the form.  THE WITNESS: I I think we keep doing	9 10 11	THE WITNESS: What's what's different about that than what I already answered? BY MS. PARFITT:
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	Page 454		Page 456
1	seen it, you've seen it. If you dispute it, you	1	probably means one thing in the world in general.
2	dispute it.	2	I think if you're talking about Rothman, yeah,
3	A Well, it's it's none of those.	3	Rothman has written about that
4	But you just said reports. Does that	4	BY MS. PARFITT:
5	are we now talking about expert reports or are	5	Q Right.
6	Q No.	6	A and about it being simply a
7	A we still talking about	7	competition of sort of counting those that are
8	Q No, we're still talking	8	significant and those that are not.
9	A Okay. We're talking about like	9	I didn't see that. I think the way I
10	peer-reviewed publications?	10	described it I think was was the way I
11	Q That's right.	11	approached it, which said some of the information
12	A So I've seen a mixture, yeah. It's like	12	that's available is that some of the studies were
13	when you look at the epi literature, I mean the	13	statistically significant and some weren't. It's
14	the way I read it is like is, you know, an	14	informative, but it's not literally the same as
15	epidemiologist is supposed to be able to get up to	15	saying, I'm just going to count them up and stop
16	speed without becoming an expert in absolutely	16	there.
17	everything, right?	17	Q Because that would be improper, correct?
18	So I already told you I'm not a cancer	18	MS. BROWN: Objection.
19	biologist, but I do count on the authors to set	19	THE WITNESS: To only do that, yes.
20	the stage with the introduction and then interpret	20	BY MS. PARFITT:
21	their findings and the discussion and sort of take	21	Q Okay. All right. Let me ask a couple
22	us at least partway towards there.	22	of question questions.
23	So even the recent meta-analysis, if you	23	What is the minimal level of exposure to
24	look at Berge or Burge (phonetic), however you say	24	cigarette smoke in terms of cigarette smoke at
25	that, and Penninkilampi, you know, they talk about	25	home that's necessary to cause lung cancer?
	Page 455		Page 457
1	there there being uncertainty about the	1	MS. BROWN: Form.
2	mechanism. So I'm just saying even as recently as	1 1	THE WITNESS: I do not know.
3		2	
	the the very latest meta-analysis, there's	3	BY MS. PARFITT:
4	uncertainty expressed.	3 4	BY MS. PARFITT:  Q Okay. What is the minimal level of
	uncertainty expressed.  Q Do you see uncertainty being expressed	3 4 5	BY MS. PARFITT:  Q Okay. What is the minimal level of exposure to asbestos fibers inhaled that is
4 5 6	uncertainty expressed.  Q Do you see uncertainty being expressed by biologically plausible mechanisms?	3 4 5 6	BY MS. PARFITT:  Q Okay. What is the minimal level of exposure to asbestos fibers inhaled that is sufficient to cause ovarian cancer?
4 5 6 7	uncertainty expressed.  Q Do you see uncertainty being expressed by biologically plausible mechanisms?  MS. BROWN: Objection.	3 4 5	BY MS. PARFITT:  Q Okay. What is the minimal level of exposure to asbestos fibers inhaled that is
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1	or	1	Q Okay. You criticize the plaintiffs'
2	BY MS. PARFITT:	2	experts for what you called a muted examination of
3	Q Pleural.	3	the case-control studies that they reviewed.
4	A So the so the amount for pleural	4	Do you remember saying that in your
5	mesothelioma is and did you say fiber type or	5	report?
6	you didn't mention fiber type?	6	A I don't remember that word, but it's
7	Q I didn't. I just said fibers.	7	it makes a lot of sense to me.
8	A Okay. So it would matter fiber type.	8	Q Okay. Where in your port report did
9	If it's chrysotile predominant, then above 200 to	9	you set forth all of the limitations and
10	400 fiber/cc years would be, you know, one	10	weaknesses of the cohort studies of talcum
11	estimate of the dose. If it's crocidolite, you	11	talcum powder products and asbestos and ovarian
12	know, you could divide that by 500. And if it's	12	cancer?
13	amosite, by a hundred, and other amphiboles, you	13	A Well, there's a bunch, right. So
14	know, somewhere in between those sort of ranges.	14	Q Well, where did you
15	And so, you know, I think for	15	A I'm telling you.
16	amphiboles, above like the single digit fiber/cc	16	Q provide us in your report that
17	years, and for chrysotile, above the couple of	17	information
18	like 200 to 400 fiber/cc years.	18	A I'm telling you.
19	Q Is it true that the dose-response curve	19	MS. BROWN: Let him finish
20	for any genotoxic carcinogen intersects with zero?	20	THE WITNESS: I understand your
21	MS. BROWN: Objection to the form.	21	question.
22	THE WITNESS: Well, there's got to be a	22	MS. BROWN: and answer your question.
23	zero point if there's zero exposure, right? If	23	THE WITNESS: So one of the criticisms,
24	there's literally zero exposure, then there can't	24	which I think is pretty profound, which is the
25	be there can't be a signal from that zero.	25	lack of a validated measure of talcum powder
	Page 459		Page 461
1	BY MS. PARFITT:	1	exposure that could have someone estimate whether
2	Q What does the what does it mean if a	2	or not somebody is exposed at all or whether or
3	dose-response curve intersects zero?	3	not there's a dose-response, and that applies to
4	MS. BROWN: Form.	4	all the studies, right. So that's uniformly
5	BY MS. PARFITT:	5	applied to whether they're case-control studies
6	Q What does that mean?	6	or or cohort studies.
7	A It's not a term that's familiar. I	7	BY MS. PARFITT:
8	mean, it's just I'm not sure if you've got	8	Q That would be the exposure
9	zero exposure, you can't have any outcome from	9	misclassification.
10	that. So I I assume that's what we're talking	10	MS. BROWN: Objection.
11	about is just like a like a no exposure	11	THE WITNESS: No, no, no. So it would
12	estimate.	12	be you could misclassify it, but it but what
13	If you're talking about like the	13	I'm talking about is, that in order to measure an
14	place I've seen people talk about it is like with	14	exposure, you need a valid measure of that
15	low doses of things and what happens, you know,	15	exposure. That doesn't exist, or at least if it
16	below the concentration or the level at which	16	exists, it hasn't been employed in the in the
17	there's known effects, then what happens between	17	published literature. And that applies to the
18	there and zero. But if it's literally zero if	18	cohort studies and the case controls.
19	there's literally zero exposure, it's got to be	19	What I what I did was I tried to
20	zero outcome.	20	actually not denigrate any of the study designs.
21	(Counsel conferring.	21	I thought that was appalling. You know, when you
21	DVAC DADRICE	22	talk about where this came from, you know, to sort
22	BY MS. PARFITT:		7.5
	Q Okay. You reviewed the cohort studies	23	of single out the cohort studies repeatedly by
22	Q Okay. You reviewed the cohort studies in this case, correct?		
22 23	Q Okay. You reviewed the cohort studies	23	of single out the cohort studies repeatedly by

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1	terrible for whatever reason, it's extraordinary,	1	Q Okay. So you would agree with me there
2	and it's to me it's unprecedented for for	2	are studies in the peer-reviewed literature that
3	epidemiologists or other healthcare professionals	3	have demonstrated a dose-response between talcum
4	to sort of look at cohort studies and find that	4	powder products and ovarian cancer?
5	those are so awful, and that case-control studies	5	MS. BROWN: Objection
6	are suddenly so sturdy. It doesn't make any	6	MR. LOCKE: Objection.
7	sense.	7	MS. BROWN: to the form.
8	So so for me, like the task wasn't	8	MS. PARFITT: Let him answer, please.
9	really so much I wasn't trying to criticize	9	MS. BROWN: I get to object.
10	either form of the study, but just to point out	10	THE WITNESS: I think just a couple.
11	realistically that there are biases, that there	11	MS. PARFITT: Let's go off the record.
12	are confounding issues, and and things of	12	THE VIDEOGRAPHER: The time is 5:53 p.m.
13	that that sort.	13	We're going off the record.
14	BY MS. PARFITT:	14	(Recess.)
15	Q In your review of the literature for	15	THE VIDEOGRAPHER: The time is 5:58 p.m.
16	purposes of your opinions today, did you see	16	We're back on the record.
17	evidence from any of the studies that you read	17	MR. HEASLIP: Can we go off for one
18	that there was a dose-response associated between	18	moment? I apologize.
19	talcum powder products and ovarian cancer?	19	THE VIDEOGRAPHER: The time is 5:58 p.m.
20	A So in total, no. In a couple of	20	We're going back off the record.
21	studies, there are purported dose-response	21	(A discussion was held off the record.)
22	findings, right. So the latest Cramer study is an	22	THE VIDEOGRAPHER: The time is 5:59 p.m.
23	example. There may have been another, but there	23	We're back on the record.
24	are so many studies that show absolutely the	24	CROSS-EXAMINATION
25	opposite, meaning either flat dose-response,	25	BY MR. FINCH:
	Page 463		Page 465
1	upside down dose-response, zig-zaggy, haphazard	1	Q Good afternoon, Dr. Diette. My name is
2	dose-response. So I would say looking at the	2	Nate Finch. You and I have met before, correct?
3	evidence in total, it's a mess. I mean it's	3	A Yes.
4	certainly not supportive.	4	Q You were asked a question about the
5	And I'll you the truth, if you go back	5	dose-response curve to genotoxic carcinogens. Do
6	to like to 2000 and I know we're in a hurry,	6	you recall that question?
7	so I will try to talk a little faster but the	7	A I do.
8	Rothman the Rothman review, at least up until	8	Q And your answer was something to the
9	2000, they they plotted out all the	9	effect of if the dose was zero, then it would be
10	dose-response they found, and they found an	10	an intersection of zero.
11	inverse relationship overall, which is one of the	11	D 11.1
			Do you recall that answer?
12	things they found to be inconsistent with there	12	A Something like that.
12 13	things they found to be inconsistent with there being causation.		
	things they found to be inconsistent with there	12	A Something like that.
13	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to	12 13	<ul><li>A Something like that.</li><li>Q All right. I want you to assume that</li></ul>
13 14	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and	12 13 14	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where
13 14 15	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and his colleagues, is actually upside down.	12 13 14 15	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where there is a positive dose, not a dose of zero.
13 14 15 16	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and his colleagues, is actually upside down.  Q What about Terry? Terry in 2013	12 13 14 15 16	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where there is a positive dose, not a dose of zero.  Your typical dose-response curve looks something
13 14 15 16 17	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and his colleagues, is actually upside down.	12 13 14 15 16 17	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where there is a positive dose, not a dose of zero.  Your typical dose-response curve looks something like this (indicating), right, with dose on the
13 14 15 16 17 18	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and his colleagues, is actually upside down.  Q What about Terry? Terry in 2013	12 13 14 15 16 17 18	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where there is a positive dose, not a dose of zero. Your typical dose-response curve looks something like this (indicating), right, with dose on the X-axis and response on the Y-axis?
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13 14 15 16 17 18 19 20	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and his colleagues, is actually upside down.  Q What about Terry? Terry in 2013 reported a dose-response, did they not?  MS. BROWN: Objection to the form.	12 13 14 15 16 17 18 19 20	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where there is a positive dose, not a dose of zero. Your typical dose-response curve looks something like this (indicating), right, with dose on the X-axis and response on the Y-axis?  A You can draw it that way.  MS. MILLER: Is that a exhibit?
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13 14 15 16 17 18 19 20 21 22	things they found to be inconsistent with there being causation.  So I think, you know, from 1982, when the first case-control study was published, to 2000, at least when it's assessed by Rothman and his colleagues, is actually upside down.  Q What about Terry? Terry in 2013 reported a dose-response, did they not?  MS. BROWN: Objection to the form.  THE WITNESS: I don't remember what they showed. I don't I don't doubt you, but I	12 13 14 15 16 17 18 19 20 21 22	A Something like that.  Q All right. I want you to assume that we're talking about a dose-response curve where there is a positive dose, not a dose of zero. Your typical dose-response curve looks something like this (indicating), right, with dose on the X-axis and response on the Y-axis?  A You can draw it that way.  MS. MILLER: Is that a exhibit?  MR. FINCH: You can mark it as an exhibit. It's got somebody's notes on the back of

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	Page 466		Page 468
1	genotoxic carcinogen where there is a positive	1	about the sort of mechanical process of writing
2	dose, the dose-response curve always intersects	2	your report. Do you remember that?
3	with zero?	3	A I do.
4	MS. BROWN: Objection to form.	4	Q And to be clear, Doctor, did you write
5	THE WITNESS: That's not something that	5	every substantive word of the expert report that
6	I say. I mean I don't people may say that, but	6	we've marked as an exhibit in this case?
7	I I think when we're talking about like zero	7	A To the yes, everything substantive.
8	is zero, right. So zero exposure means zero risk.	8	Q Did MSA or Medical Science Affiliates
9	BY MR. FINCH:	9	make any substantive contributions to your expert
10	Q I'm not I'm not talking about zero.	10	report in this proceeding?
11	MS. BROWN: Wait, let him finish,	11	A No.
12		12	Q You spoke a little bit earlier today
13	please.	13	about some administrative support that you
14	THE WITNESS: Well, I know. That's what	14	received from MSA. Do you remember that?
15	I'm talking about when I when I hear that	15	A I do.
	question.	16	Q And tell us what you meant by
16	BY MR. FINCH:	17	"administrative support."
17	Q All right. So if someone were to	18	A So by "administrative support," I meant,
18	testify when you're talking about a genotoxic		
19	carcinogen where there is a positive exposure,	19	you know, gathering like collating materials
20	there the dose-response curve intersects with	20	for me, helping to to format the report, you
21	zero, meaning that there isn't it true that	21	know, putting you know, putting the reference
22	that means that there at any level of exposure,	22	citations in correctly. You know, creating the
23	there's an excess risk of cancer for a genotoxic	23	the list of reliance documents at the end. You
24	carcinogen?	24	know, things of that sort. And then and then
25	MS. BROWN: Objection to the form.	25	generating invoices.
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1	THE WITNESS: So I don't know. That may	1	I'm trying to think what else.
2	be part of some field that's not my field. But I	2	Whatever whatever I said earlier was the was
3	but in the fields that I work in, I recognize	3	the full list, I think.
4	that you need a certain amount of exposure in	4	Q You also mentioned earlier today
5	order to cause a disease, including cancer.	5	receiving some editorial support from the folks at
6	BY MR. FINCH:	6	MSA. Tell us what you meant by that.
7	Q Okay. But you cannot dispute that	7	A So to look for typos or I gave the
8	genotoxic carcinogens, the dose-response curve	8	example of like where I had a really long
9	intersects with zero. You haven't studied that	9	paragraph, and they broke it up with bullets to
10	issue; is that correct?	10	make it look more readable, that sort of thing,
11	MR. LOCKE: Objection.	11	and and instruction this actually bear the
	Witt. EOCKE. Objection.		and and just making this actually have the
12	MS. BROWN: Objection to the form.	12	physical appearance that it does.
12 13	ž		
	MS. BROWN: Objection to the form.	12	physical appearance that it does.
13	MS. BROWN: Objection to the form. THE VIDEOGRAPHER: Seven hours.	12 13	physical appearance that it does.  Q Did MSA provide anything other than
13 14	MS. BROWN: Objection to the form. THE VIDEOGRAPHER: Seven hours. MS. BROWN: You're done. Wait.	12 13 14	physical appearance that it does.  Q Did MSA provide anything other than administrative formatting type support in
13 14 15	MS. BROWN: Objection to the form. THE VIDEOGRAPHER: Seven hours. MS. BROWN: You're done. Wait. THE WITNESS: So I mean, my answer is	12 13 14 15	physical appearance that it does.  Q Did MSA provide anything other than administrative formatting type support in connection with your report in this case?
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### Case 3:16-md-02738-MAS-RLS Document 9895-3 Filed 05/30/19 Page 492 of 565 PageID: 71736

Gregory B. Diette, M.D.

1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER 2 The undersigned Certified Shorthand Reporter 3 does hereby certify: 4 That the foregoing proceeding was taken before 5 me at the time and place therein set forth, at 6 which time the witness was duly sworn; That the 7 testimony of the witness and all objections made 8 at the time of the examination were recorded 9 stenographically by me and were thereafter 9 stenographically by me and were thereafter 10 transcribed, said transcript being a true and 10 REASON: 11 correct copy of my shorthand notes thereof; That 12 the dismantling of the original transcript will 12 REASON: 13 void the reporter's certificate. 14 In witness thereof, I have subscribed my name 15 REASON: 16 REASON: 17 REASON: 18 REASON: 19 REASON: 10 REASON: 11 REASON: 11 REASON: 11 REASON: 12 REASON: 13 REASON:		Page 470		Page 472
THE WITNESS: They're – they're all my opinions.  BY MS. BROWN:  Q If someone were to suggest that MSA owrote some of the substantive pieces of your report, would that be the truth?  MS. PARITT: Objection. THE WITNESS: No. MS. BROWN:  MS. PARITT: Anjbody? No. Thank you. Dr. Diette, Inak you very much for your thank you very mach you return the original errar as beet to the daposing attract sheet and date it.  MS. PARITT: Anjbody? No. Thank you. Dr. Diette, Inak you very much for your thank you were much of your thank you were much of your thank you were much of your enturn the original errar as beet to the deposing attorney within thiny (30) days of the your fail to do so, the deposition transcript way be deemed to be accurate and may be used in count.  Page 471  CERTIFICATE OF CERTIFIED SHORTHAND REPORTER CONCINCIAN DEPORTER CONCINCIAN DE	1	MS. PARFITT: Objection.	1	INSTRUCTIONS TO WITNESS
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MS. PARPITT: Objection.  9	7		7	
THE WITNESS: No.  MS. BROWN: Thanks very much for your time, Dr. Diette. I have no further questions.  MS. PARFITT: Anybody? No. Thank you.  Dr. Diette, thank you very much.  MS. PARFITT: Anybody? No. Thank you.  MS. PARFITT: Anybody? No. Thank you.  MS. PARFITT: Anybody? No. Thank you.  MS. PARFITT: I appreciate it.  THE WITNESS: Thank you.  MS. PARFITT: I appreciate it.  THE WIDGGRAPHER: The time is 6:04  p.m., April 9th, 2019. Going off the record, completing the videotaped deposition.  Whereupon, the deposition of 19  GREGORY B. DIETTE, M.D. was 20  GREGORY B. DIETTE, M.D. was 22  and 24  25  Page 471  CERTIFICATE OF CERTIFIED SHORTHAND REPORTER 2 The undersigned Certified Shorthand Reporter 3 does hereby certify:  The undersigned Certified Shorthand Reporter 4 the time and place therein set forth, at 4 the foregoing proceeding was taken before 8 at the time and place therein set forth, at 4 the time of the examination were recorded 8 stenographically by me and were thereafter 1 the dismantling of the original transcript will 12 the dismantling of the original transcript will 13 void the reporter's certificate No. 5129  (The foregoing certification of the certificate stranscript will 14 transcript does not apply to any reproduction of the same by any means, 24 subservised of the certificate of th	8	• •	8	You are signing same subject to the changes
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Gregory B. Diette, M.D.

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2	I,, do hereby	
3	certify that I have read the foregoing pages, and	
4	that the same is a correct transcription of the	
5	answers given by me to the questions therein	
6	propounded, except for the corrections or changes	
7	in form or substance, if any, noted in the	
8	attached Errata Sheet.	
9		
10		
11	GREGORY B. DIETTE, M.D. DATE	
12		
13		
14	Subscribed and sworn to	
15	before me this	
16	day of,20	
17	My commission expires:	
18		
19	Notary Public	
20		
21		
22		
23		
24		
25		

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Gregory B. Diette, M.D.

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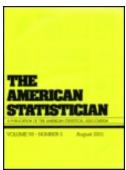
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# Exhibit 142



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# The ASA's Statement on *p*-Values: Context, Process, and Purpose

Ronald L. Wasserstein & Nicole A. Lazar

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#### **EDITORIAL**

# The ASA's Statement on p-Values: Context, Process, and Purpose

In February 2014, George Cobb, Professor Emeritus of Mathematics and Statistics at Mount Holyoke College, posed these questions to an ASA discussion forum:

- Q: Why do so many colleges and grad schools teach p = 0.05?
- A: Because that's still what the scientific community and journal editors use.
- Q: Why do so many people still use p = 0.05?
- A: Because that's what they were taught in college or grad school.

Cobb's concern was a long-worrisome circularity in the sociology of science based on the use of bright lines such as p < 0.05: "We teach it because it's what we do; we do it because it's what we teach." This concern was brought to the attention of the ASA Board.

The ASA Board was also stimulated by highly visible discussions over the last few years. For example, ScienceNews (Siegfried 2010) wrote: "It's science's dirtiest secret: The 'scientific method' of testing hypotheses by statistical analysis stands on a flimsy foundation." A November 2013, article in Phys.org Science News Wire (2013) cited "numerous deep flaws" in null hypothesis significance testing. A ScienceNews article (Siegfried 2014) on February 7, 2014, said "statistical techniques for testing hypotheses ... have more flaws than Facebook's privacy policies." A week later, statistician and "Simply Statistics" blogger Jeff Leek responded. "The problem is not that people use P-values poorly," Leek wrote, "it is that the vast majority of data analysis is not performed by people properly trained to perform data analysis" (Leek 2014). That same week, statistician and science writer Regina Nuzzo published an article in Nature entitled "Scientific Method: Statistical Errors" (Nuzzo 2014). That article is now one of the most highly viewed Nature articles, as reported by altmetric.com (http://www.altmetric.com/details/2115792#score).

Of course, it was not simply a matter of responding to some articles in print. The statistical community has been deeply concerned about issues of *reproducibility* and *replicability* of scientific conclusions. Without getting into definitions and distinctions of these terms, we observe that much confusion and even doubt about the validity of science is arising. Such doubt can lead to radical choices, such as the one taken by the editors of *Basic and Applied Social Psychology*, who decided to ban *p*-values (null hypothesis significance testing) (Trafimow and Marks 2015). Misunderstanding or misuse of statistical inference is only one cause of the "reproducibility crisis" (Peng 2015), but to our community, it is an important one.

When the ASA Board decided to take up the challenge of developing a policy statement on *p*-values and statistical significance, it did so recognizing this was not a lightly taken step. The ASA has not previously taken positions on specific matters of statistical practice. The closest the association has come to this is a statement on the use of value-added models (VAM) for educational assessment (Morganstein and Wasserstein

2014) and a statement on risk-limiting post-election audits (American Statistical Association 2010). However, these were truly policy-related statements. The VAM statement addressed a key educational policy issue, acknowledging the complexity of the issues involved, citing limitations of VAMs as effective performance models, and urging that they be developed and interpreted with the involvement of statisticians. The statement on election auditing was also in response to a major but specific policy issue (close elections in 2008), and said that statistically based election audits should become a routine part of election processes.

By contrast, the Board envisioned that the ASA statement on *p*-values and statistical significance would shed light on an aspect of our field that is too often misunderstood and misused in the broader research community, and, in the process, provides the community a service. The intended audience would be researchers, practitioners, and science writers who are not primarily statisticians. Thus, this statement would be quite different from anything previously attempted.

The Board tasked Wasserstein with assembling a group of experts representing a wide variety of points of view. On behalf of the Board, he reached out to more than two dozen such people, all of whom said they would be happy to be involved. Several expressed doubt about whether agreement could be reached, but those who did said, in effect, that if there was going to be a discussion, they wanted to be involved.

Over the course of many months, group members discussed what format the statement should take, tried to more concretely visualize the audience for the statement, and began to find points of agreement. That turned out to be relatively easy to do, but it was just as easy to find points of intense disagreement.

The time came for the group to sit down together to hash out these points, and so in October 2015, 20 members of the group met at the ASA Office in Alexandria, Virginia. The 2-day meeting was facilitated by Regina Nuzzo, and by the end of the meeting, a good set of points around which the statement could be built was developed.

The next 3 months saw multiple drafts of the statement, reviewed by group members, by Board members (in a lengthy discussion at the November 2015 ASA Board meeting), and by members of the target audience. Finally, on January 29, 2016, the Executive Committee of the ASA approved the statement.

The statement development process was lengthier and more controversial than anticipated. For example, there was considerable discussion about how best to address the issue of multiple *potential* comparisons (Gelman and Loken 2014). We debated at some length the issues behind the words "a *p*-value near 0.05 taken by itself offers only weak evidence against the null

hypothesis" (Johnson 2013). There were differing perspectives about how to characterize various alternatives to the p-value and in how much detail to address them. To keep the statement reasonably simple, we did not address alternative hypotheses, error types, or power (among other things), and not everyone agreed with that approach.

As the end of the statement development process neared, Wasserstein contacted Lazar and asked if the policy statement might be appropriate for publication in The American Statistician (TAS). After consideration, Lazar decided that TAS would provide a good platform to reach a broad and general statistical readership. Together, we decided that the addition of an online discussion would heighten the interest level for the TAS audience, giving an opportunity to reflect the aforementioned controversy.

To that end, a group of discussants was contacted to provide comments on the statement. You can read their statements in the online supplement, and a guide to those statements appears at the end of this editorial. We thank Naomi Altman, Douglas Altman, Daniel J. Benjamin, Yoav Benjamini, Jim Berger, Don Berry, John Carlin, George Cobb, Andrew Gelman, Steve Goodman, Sander Greenland, John Ioannidis, Joseph Horowitz, Valen Johnson, Michael Lavine, Michael Lew, Rod Little, Deborah Mayo, Michele Millar, Charles Poole, Ken Rothman, Stephen Senn, Dalene Stangl, Philip Stark and Steve Ziliak for sharing their insightful perspectives.

Of special note is the following article, which is a significant contribution to the literature about p-values and statistical significance.

Greenland, S., Senn, S.J., Rothman, K.J., Carlin, J.B., Poole, C., Goodman, S.N. and Altman, D.G.: "Statistical Tests, P-values, Confidence Intervals, and Power: A Guide to Misinterpretations."

Though there was disagreement on exactly what the statement should say, there was high agreement that the ASA should be speaking out about these matters.

Let us be clear. Nothing in the ASA statement is new. Statisticians and others have been sounding the alarm about these matters for decades, to little avail. We hoped that a statement from the world's largest professional association of statisticians would open a fresh discussion and draw renewed and vigorous attention to changing the practice of science with regards to the use of statistical inference.

# **Guide to the Online Supplemental Material to the ASA** Statement on P-Values and Statistical Significance

Many of the participants in the development of the ASA statement contributed commentary about the statement or matters related to it. Their comments are posted as online supplements to the statement. We provide here a list of the supplemental articles.

# **Supplemental Material to the ASA Statement on** P-Values and Statistical Significance

• Altman, Naomi: Ideas from multiple testing of high dimensional data provide insights about reproducibility and false discovery rates of hypothesis supported by *p*-values

- Benjamin, Daniel J, and Berger, James O: A simple alternative to p-values
- *Benjamini*, *Yoav*: It's not the *p*-values' fault
- Berry, Donald A: P-values are not what they're cracked up
- Carlin, John B: Comment: Is reform possible without a paradigm shift?
- Cobb, George: ASA statement on p-values: Two consequences we can hope for
- Gelman, Andrew: The problems with p-values are not just with *p*-values
- Goodman, Steven N: The next questions: Who, what, when, where, and why?
- Greenland, Sander: The ASA guidelines and null bias in current teaching and practice
- Ioannidis, John P.A.: Fit-for-purpose inferential methods: abandoning/changing P-values versus abandoning/changing research
- Johnson, Valen E.: Comments on the "ASA Statement on Statistical Significance and P-values" and marginally significant *p*-values
- Lavine, Michael, and Horowitz, Joseph: Comment
- Lew, Michael J: Three inferential questions, two types of P-value
- Little, Roderick J: Discussion
- Mayo, Deborah G: Don't throw out the error control baby with the bad statistics bathwater
- Millar, Michele: ASA statement on p-values: some implications for education
- Rothman, Kenneth J: Disengaging from statistical signifi-
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Ronald L. Wasserstein and Nicole A. Lazar

non@amstat.org

American Statistical Association, 732 North Washington Street, Alexandria, VA 22314-1943.

# ASA Statement on Statistical Significance and *P*-Values

#### 1. Introduction

Increased quantification of scientific research and a proliferation of large, complex datasets in recent years have expanded the scope of applications of statistical methods. This has created new avenues for scientific progress, but it also brings concerns about conclusions drawn from research data. The validity of scientific conclusions, including their reproducibility, depends on more than the statistical methods themselves. Appropriately chosen techniques, properly conducted analyses and correct interpretation of statistical results also play a key role in ensuring that conclusions are sound and that uncertainty surrounding them is represented properly.

Underpinning many published scientific conclusions is the concept of "statistical significance," typically assessed with an index called the p-value. While the p-value can be a useful statistical measure, it is commonly misused and misinterpreted. This has led to some scientific journals discouraging the use of p-values, and some scientists and statisticians recommending their abandonment, with some arguments essentially unchanged since *p*-values were first introduced.

In this context, the American Statistical Association (ASA) believes that the scientific community could benefit from a formal statement clarifying several widely agreed upon principles underlying the proper use and interpretation of the *p*-value. The issues touched on here affect not only research, but research funding, journal practices, career advancement, scientific education, public policy, journalism, and law. This statement does not seek to resolve all the issues relating to sound statistical practice, nor to settle foundational controversies. Rather, the statement articulates in nontechnical terms a few select principles that could improve the conduct or interpretation of quantitative science, according to widespread consensus in the statistical community.

## 2. What is a p-Value?

Informally, a p-value is the probability under a specified statistical model that a statistical summary of the data (e.g., the sample mean difference between two compared groups) would be equal to or more extreme than its observed value.

#### 3. Principles

1. P-values can indicate how incompatible the data are with a specified statistical model.

A p-value provides one approach to summarizing the incompatibility between a particular set of data and

a proposed model for the data. The most common context is a model, constructed under a set of assumptions, together with a so-called "null hypothesis." Often the null hypothesis postulates the absence of an effect, such as no difference between two groups, or the absence of a relationship between a factor and an outcome. The smaller the p-value, the greater the statistical incompatibility of the data with the null hypothesis, if the underlying assumptions used to calculate the p-value hold. This incompatibility can be interpreted as casting doubt on or providing evidence against the null hypothesis or the underlying assumptions.

# 2. P-values do not measure the probability that the studied hypothesis is true, or the probability that the data were produced by random chance alone.

Researchers often wish to turn a p-value into a statement about the truth of a null hypothesis, or about the probability that random chance produced the observed data. The p-value is neither. It is a statement about data in relation to a specified hypothetical explanation, and is not a statement about the explanation itself.

## Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold.

Practices that reduce data analysis or scientific inference to mechanical "bright-line" rules (such as "p < 0.05") for justifying scientific claims or conclusions can lead to erroneous beliefs and poor decision making. A conclusion does not immediately become "true" on one side of the divide and "false" on the other. Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis. Pragmatic considerations often require binary, "yes-no" decisions, but this does not mean that p-values alone can ensure that a decision is correct or incorrect. The widespread use of "statistical significance" (generally interpreted as " $p \le 0.05$ ") as a license for making a claim of a scientific finding (or implied truth) leads to considerable distortion of the scientific process.

# 4. Proper inference requires full reporting and transparency

P-values and related analyses should not be reported selectively. Conducting multiple analyses of the data and reporting only those with certain p-values (typically those passing a significance threshold) renders the 132 ( EDITORIAL

reported *p*-values essentially uninterpretable. Cherrypicking promising findings, also known by such terms as data dredging, significance chasing, significance questing, selective inference, and "p-hacking," leads to a spurious excess of statistically significant results in the published literature and should be vigorously avoided. One need not formally carry out multiple statistical tests for this problem to arise: Whenever a researcher chooses what to present based on statistical results, valid interpretation of those results is severely compromised if the reader is not informed of the choice and its basis. Researchers should disclose the number of hypotheses explored during the study, all data collection decisions, all statistical analyses conducted, and all p-values computed. Valid scientific conclusions based on p-values and related statistics cannot be drawn without at least knowing how many and which analyses were conducted, and how those analyses (including *p*-values) were selected for reporting.

# 5. A p-value, or statistical significance, does not measure the size of an effect or the importance of a result.

Statistical significance is not equivalent to scientific, human, or economic significance. Smaller *p*-values do not necessarily imply the presence of larger or more important effects, and larger p-values do not imply a lack of importance or even lack of effect. Any effect, no matter how tiny, can produce a small p-value if the sample size or measurement precision is high enough, and large effects may produce unimpressive p-values if the sample size is small or measurements are imprecise. Similarly, identical estimated effects will have different *p*-values if the precision of the estimates

# 6. By itself, a p-value does not provide a good measure of evidence regarding a model or hypothesis.

Researchers should recognize that a p-value without context or other evidence provides limited information. For example, a *p*-value near 0.05 taken by itself offers only weak evidence against the null hypothesis. Likewise, a relatively large *p*-value does not imply evidence in favor of the null hypothesis; many other hypotheses may be equally or more consistent with the observed data. For these reasons, data analysis should not end with the calculation of a p-value when other approaches are appropriate and feasible.

#### 4. Other Approaches

In view of the prevalent misuses of and misconceptions concerning *p*-values, some statisticians prefer to supplement or even replace p-values with other approaches. These include methods that emphasize estimation over testing, such as confidence, credibility, or prediction intervals; Bayesian methods; alternative measures of evidence, such as likelihood ratios or Bayes Factors; and other approaches such as decision-theoretic modeling and false discovery rates. All these measures and approaches rely on further assumptions, but they may more directly address the size of an effect (and its associated uncertainty) or whether the hypothesis is correct.

#### 5. Conclusion

Good statistical practice, as an essential component of good scientific practice, emphasizes principles of good study design and conduct, a variety of numerical and graphical summaries of data, understanding of the phenomenon under study, interpretation of results in context, complete reporting and proper logical and quantitative understanding of what data summaries mean. No single index should substitute for scientific reasoning.

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